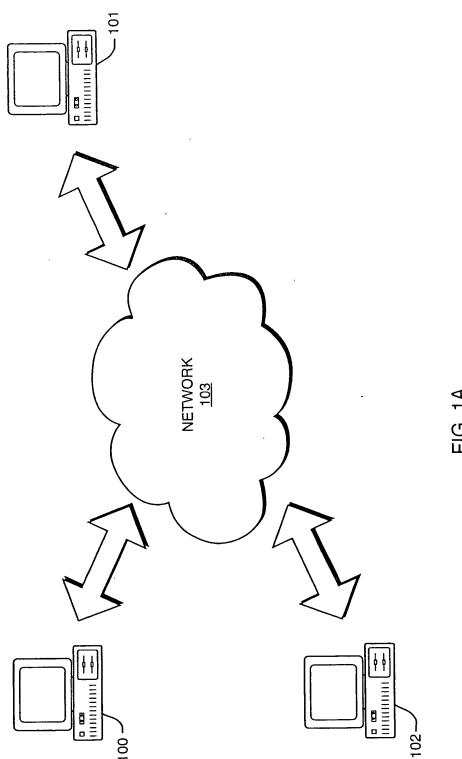
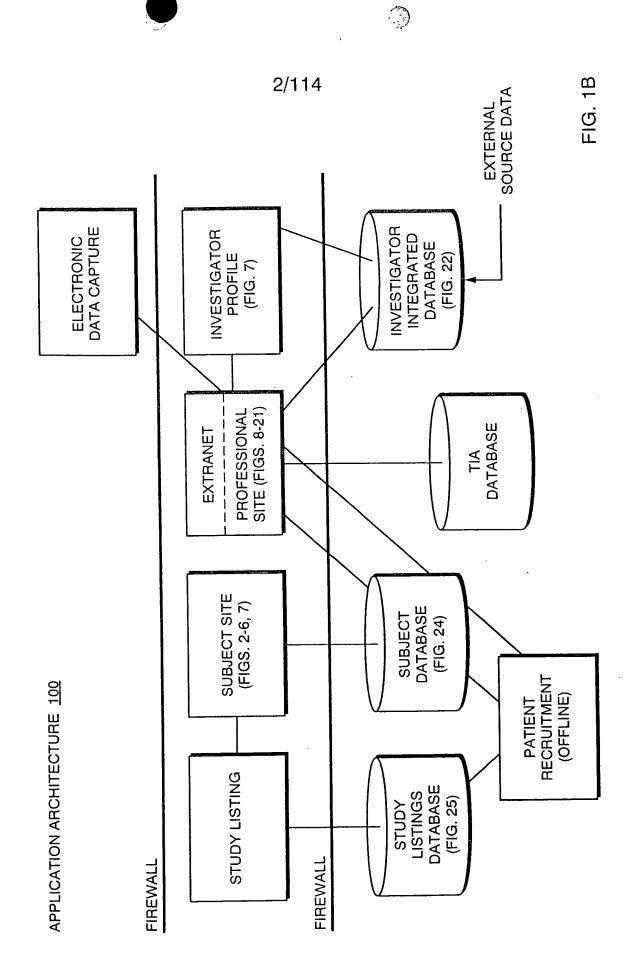




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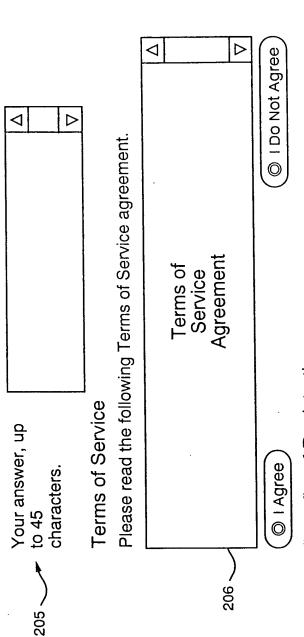




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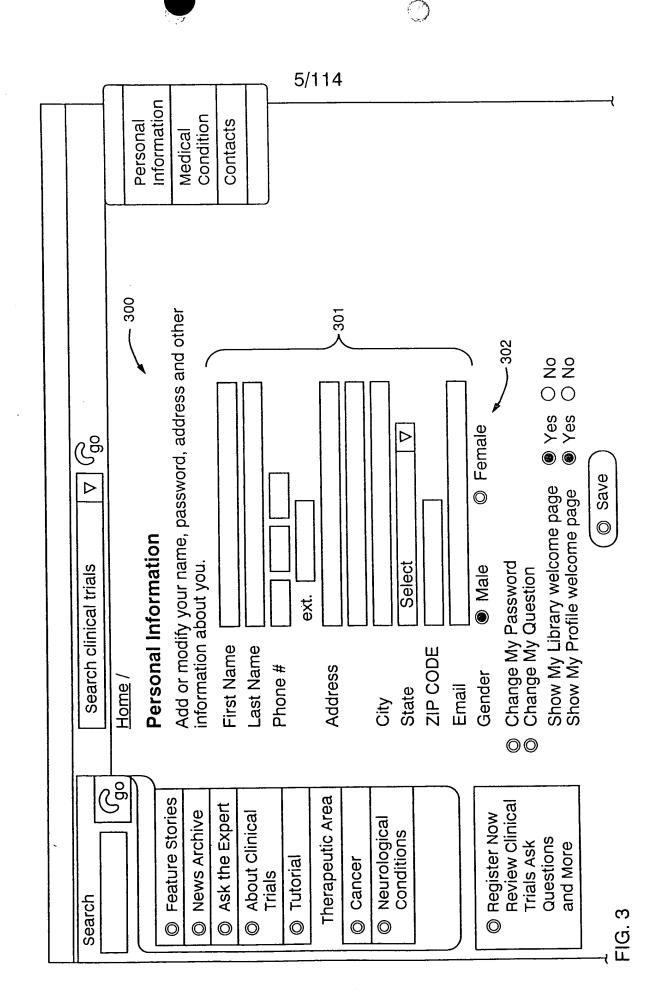
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Benefits of Registration

Registered users will benefit from:

- Our comprehensive clinical trial listings get trial information and find out how you can be considered for participation in clinical trials.
- The ability to ask questions of our medical experts.
- Timely, relevant announcements of new trials and drug information. 0
- Exclusive interactive tools, including your own personal library of news information. 0
- Emails informing you of updates to our clinical trial listings, news and information, tailored to your selection. 0
- A personal profile used to optimize your experience.



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FIG. 4A

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Introduction: What are clinical trials?

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Quite simply, a clinical trial is a very carefully structured study that evaluates the effectiveness of a drug against a specific disease or condition. Clinical trials can focus on a new drug or they may be used to determine new uses for existing medications.

When a promising new medication is identified, the drug undergoes careful evaluation for safety and effectiveness through the clinical trial process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. The pharmaceutical or biotechnology company that is sponsoring the trial reports their findings to the U.S. Food and Drug Administration (FDA). The FDA reviews those findings and if they determine that the drug is both effective and safe to use, then they will make the drug available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial.

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If you are looking for clinical trials that may be beneficial for you, please search our clinical trials listing for details on type and location. This is the first step to review the exciting medical research on the potential new treatments of tomorrow that may benefit you today.

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Back to top

Why are clinical trials important?

Clinical trials are important to increase medical knowledge and find better ways to help people. Generally, the goal of clinical trials is to introduce an investigational treatment that is safer and more effective than the standard treatment for a particular disease or condition. In addition, for those diseases for which there are no treatment options, research and clinical trials may be the only avenue to uncover a potential treatment.

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The clinical trial process.

After a drug is successfully tested in laboratory and animal studies, the FDA grants approval for testing to begin in humans. The testing of drugs in clinical trials - also called clinical studies or clinical research - usually occurs in three and sometimes four different phases or steps. Each phase normally involves a larger number of people.

Phase I. In Phase I trials, researchers study how quickly an investigational treatment works and how the human body processes the investigational treatment. They also try to find dose ranges that will produce the desired effects. Phase I trials typically involve healthy volunteers, but sometimes severely ill patients will participate in these

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Phase II. In these trials, the safety and effectiveness of an investigational treatment is studied in larger groups of people who have the disease or condition to be treated.

phase III. In Phase III trials, the safety and effectiveness of an investigational treatment are studied in larger populations of people for whom the drug is intended.

Typically, there are hundreds or thousands of people in a Phase III trial. Often, the investigational treatment is compared with standard treatments in hopes of finding better ways to help people. The pharmaceutical or biotechnology company that is sponsoring the trial reports the findings from Phase III trials to the U.S. Food and Drug Administration (FDA).

Phase IV. Phase IV trials are also called post-marketing trials. Only after the FDA has determined that the medicine is both safe to use and equivalent or superior to existing therapies is it then made available for broader use by physicians and their patients. Phase IV trials take place after a drug has been approved. Findings from Phase IV trials provide additional information about the safety and efficacy of the drug.

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How are participant's rights and safety protected during a clinical trial?

The FDA is the government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The rights and safety of people participating in clinical trials are also protected by an Institutional Review Board and by an informed consent form. An Institutional Review Board (IRB) is comprised of both physicians and lay people for the purpose of studying the design of the trial and ensuring that participant's rights are maintained. The informed consent form explains the clinical trial and outlines a participant's rights. You should always be given an informed consent form prior to enrolling in any clinical trial.

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Who pays for clinical trials?

- Sponsors fund clinical trials. This funding can come from the federal government via the National Institutes of Health (NIH) or directly from pharmaceutical and biotech companies.
- The clinical trial sponsor contracts with specialized physicians and/or researchers to administrate the trial. Settings for the trials could range from the physician's office to a hospital or research facility. Reimbursement for this service is typically paid out on a per-patient basis.

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Sponsors may pay you to participate in a clinical trial. Typically, these fees, when provided, are nominal

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expenses such as travel between their homes and patients, but they still may be responsible for other Medical care is often provided at no cost to the the health care facility.

a part of standard treatment and not part of the clinical trial. procedures, tests, or hospital stays if these are considered Before you enroll, you should determine exactly who pays Patients may also have to pay for some medical for what services Back to top

Where can you get more information about clinical

If you or someone you know has a medical problem and is management of your health, you may want to work closely with your provider to find out if a particular clinical trial is thinking about taking part in a clinical trial, speak to your health care provider first. In taking an active role in the right for you. Back to top

Questions you need to ask.

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- What is the length of your involvement in the clinical trial? How long will the trial last?
 - Where will you have to go in order to participate in the clinical trial?
- What are the possible treatments you may receive while in the clinical trial?
- possible treatments for this disease? If not, what are Do the treatment alternatives they provide cover all your other treatment alternatives ?
 - What procedures are built into the study to keep you safe from harm while you are participating?
- What are the risks and benefits of participating in the clinical trial?
 - If there are risks, what will happen should you have an adverse reaction to the treatment in the study ? What costs may you incur if you participate ?
- Will the treatment be available to you even after the clinical trial has concluded?
- trial? What is their purpose in sponsoring the trial? Where are the funds coming from to conduct this

You should also feel free to ask any other question about the trial you want answered Back to top

Common terms used in clinical trials.

Clinical trial: A clinical trial - also called a clinical study or clinical research - is a way to evaluate the safety and benefits of a new drug in a carefully controlled setting. The new drug is tested in people who volunteer to participate in the trial.

Clinical investigator: A clinical investigator is a doctor or scientist who is responsible for carrying out the planned research activities for a clinical trial. Typically, the doctors chosen for these clinical activities are experts within their medical specialties.

Coordinator: A coordinator is a person (usually a nurse or other medical professional) who is responsible for organizing the planned clinical research activities for a trial. The coordinator is also responsible for taking care of important study documents.

Food and Drug Administration: The Food and Drug Administration is often referred to as the FDA. The FDA is a government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The FDA also enforces the laws that govern the approval, regulation and monitoring of drugs and medical devices.

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Informed Consent: Informed consent is a process that confirms a patient understands the nature of a study, the risks involved, and the expected benefits of treatment. A written and dated form called the "informed consent form" is signed by a patient to document this process.

Institutional Review Board: An Institutional Review Board is usually referred to as the "IRB." The IRB is a group of medical, scientific, and nonscientific people that are responsible for reviewing and approving the planned clinical activities of a study. The group ensures the protection of the rights, safety, and well-being of patients who volunteer for clinical trials.

Investigational treatment: Investigational treatment is another term for the drug, treatment, or medical device that is studied in a clinical trial.

Principal investigator: The principal investigator is the doctor or researcher who is put in charge of all clinical activities at a particular study location and who supervises the care of patients in the study.

Protocol: A protocol is a plan that contains guidelines for a clinical study. The pharmaceutical or biotechnology company that discovered the investigational treatment usually develops the protocol.

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Sponsor: The sponsor is the organization that funds a clinical trial and that develops a plan for the research. organizations can be a pharmaceutical or biotech company, a research institution, or other health organization.

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be effective against a particular disease, then no treatment given disease. If there are no current treatments shown to conditions. It is the "best treatment" currently known for a Standard treatment: Standard treatment is a term that refers to approved medical procedures, drugs, tests, or considered to be appropriate for certain diseases and would be the standard treatment for that condition. hospitalizations that are a part of the general care

FIG. 5J

Back to top

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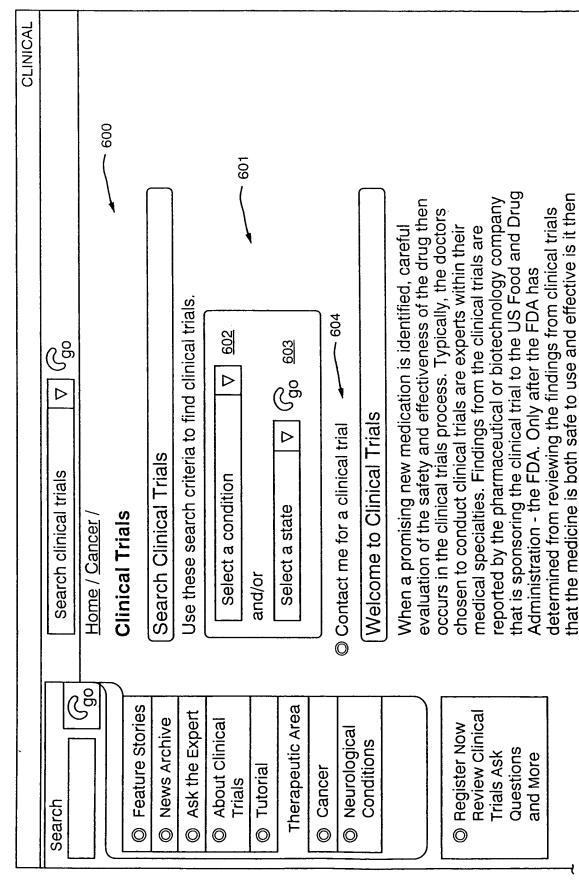


FIG. 6A

made available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial

If you are looking for information on where clinical trials are taking place and the types of trials that are available, you can search our clinical trials listing. If you want to learn more about clinical trials, please see our About Clinical Trials page. These are the first steps in learning about clinical trials and in deciding how medical research on possible treatments for tomorrow may help you today.

About Clinical Trials will provide you with more information.

FIG. 6B

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FIG. 6C

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FIG. 6D

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 \triangleright we invite you to compute the following questionnaire Your privacy and security are very important to us; therefore we encourage you will use the information to present you with new medical What is your mother's maiden name? Step 1 of 3 about you and your health. This should take approximately 5 minutes to Are you seeking information for yourself, or for someone else? therapy and clinical trial information that is of specific interest to you. I am seeking information for someone else I am seeking information for myself **Choose Your Username and Password** නී Continue to review our Privacy & Security Policy. Please enter your answer to the Choose your reminder question Please re-type your password \triangleright Please choose a username Please choose a password Search clinical trials To register with question Welcome! Register complete. ڹڰؙؙ Eeature Articles Therapeutic Area Ask the Expert Review Clinical Medical News **Clinical Trials** Register Now Neurological Conditions Questions **Trials Ask** and More All About Tutorial Cancer Search 0 0 0

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FIG. 6E

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FIG 6F

Alopecia (Hair Loss) Cancer: Prostate Seizures (Epilepsy)

My Conditions:

I do not want to receive information by e-mail.

Medical Conditions By completing this section, you will help us to provide you with information that meets your interests.

I am interested in the following conditions * (you may choose more than one):

< Remove Add > Alopecia (Hair Loss) Medical Conditions: * Acne AIDS/HIV Allergies

Continue

FIG. 6G

Step 3 of 3 By selecting "I Accept", you are accepting the Terms and Conditions above and will become a registered user. 4 Please read the following Terms and Conditions Agreement. I would like to receive information about my conditions: I Do Not Accept Send me News and New Medical Therapies Send me News and New Medical Therapies Send me News and New Medical Therapies TERMS AND CONDITIONS Seizures (Epilepsy):
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FIG. 6H

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FIG. 61

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FIG. 6J

| Search | Search clinical trials ∇ |
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| 8 | Health Habits (Optional) |
| © Feature Articles | It is often important to know your health habits when presenting you with possible clinical trial opportunities. |
| Medical NewsAsk the Expert | How often do you exercise? |
| All About Clinical Trials | Once a weekTwice a week |
| | Three times a weekFour or more times a week |
| Therapeutic Area | □ Daily |
| © cancer | How often do vou visit your primary care physician ? |
| Neurological Conditions | © Once a year |
| | Every monthI do not have a primary care physician |
| © Register Now Review Clinical Trials Ask | Do you smoke cigarettes ? © No, I have never smoked © No, I quit smoking |
| and More | • |

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| If you smoke, how many cigarettes do you smoke per day? Please enter: Cigarettes Per Day If you smoke, how old were you when you started smoking? Please enter: years old Do you drink alcoholic beverages? No Yes, occasionally Yes, 1-2 drinks per day Yes, more than 2 drinks per day Overall, how would you rate your health? Excellent Good Payer Proportion of the per day Overall, how would you rate your health? Excellent Good Payer Proportion of the per day Overall of the per day O | Save and Return to Previous Activity |
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| Search | Search clinical trials ∇ |
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| - B | Clinical Trial Experience (Optional) Step 3 of 5 |
| © Feature Articles © Medical News | A clinical trial is a carefully structured study that evaluates the effectiveness of a drug against a specific disease or condition. Clinical trials can focus on a new drug or they may be used to determine new uses for existing medications. |
| Ash the Expert All About Clinical Trials Tutorial | The following questions ask about your experience and interest in participating in clinical trials. These questions are to help us know how many members of ours have participated in clinical trials before. |
| Therapeutic Area Cancer Neurological Conditions | How many clinical trials have you participated in ? |
| © Register Now Review Clinical Trials Ask Questions and More | How interested would you be in participating in a clinical trial for a drug that might be used to treat any medical condition(s) you may have ? Very interested Somewhat interested Not Sure |

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If interested in clinical trial participation how far would you be willing to travel to participate in a clinical trial?

- 1 10 miles
 11 50 miles
 51 100 miles
 More than 100 miles
 Any distance

Save and Continue

Save and Return to Previous Activity

FIG. 6N

| Search Search clinical trials Clinical Trial Questions Clinical Trial Questions Clinical Trial Questions Clinical Trials All About Clinical Trials Therapeutic Area Conditions Register Now Register Now Review Clinical Review Clinical Conditions Conditions | |
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| Feature Articles Medical News Ask the Expert All About Clinical Trials Tutorial herapeutic Area Cancer Neurological Conditions Register Now Register Now Review Clinical Trials Ask Questions | Questions Step 4 of 5 |
| Medical News Ask the Expert All About Clinical Trials Tutorial Derapeutic Area Cancer Neurological Conditions Register Now Review Clinical Trials Ask Questions | gistration process, you expressed interest in clinical |
| Ask the Expert All About Clinical Trials Tutorial Perapeutic Area Cancer Neurological Conditions Register Now Review Clinical Trials Ask Questions | Then you are screened for a cillingal trial, the doctor ow more information about your health and the me |
| All About Clinical Trials Tutorial Perapeutic Area Cancer Neurological Conditions Register Now Review Clinical Trials Ask Questions | which you have been diagnosed. Your answers to t |
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| Cancer Neurological Conditions Register Now Review Clinical Trials Ask Questions | e the conditions you selected earlier in the question |
| Cancer Neurological Conditions Register Now Review Clinical Trials Ask Questions | stions about each condition, a cneck mark will app mation will be saved after you complete each section |
| Neurological Conditions Conditions Condition Alopecia (Hair Loss) Cancer: Prostate Seizures (Epilepsy) Trials Ask Questions | lete these at this time, we will ask you to update yo |
| Conditions Condition Alopecia (Hair Loss) Cancer: Prostate Seizures (Epilepsy) Trials Ask Questions | |
| Register Now Review Clinical Trials Ask Questions Condition Alopecia (Hair Loss) Cancer: Prostate Seizures (Epilepsy) Seizures (Epilepsy) Seizures (Epilepsy) Seizures (Epilepsy) | Questionnaire |
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FIG. 6P

| Search | Search clinical trials ∇ \bigcirc Thank You Your message was sent successfully. Thank you for contacting us. Your comments will help us serve you better. Return to Previous Activity |
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| Questions and More | |
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FIG. 60

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| <u>ති </u> | | Icome to My Library | Here's your chance to create a library of your very own. My | Library is where you can store all kinds of information | found throughout the site. Whether it's climbal that | perspectives from our medical experts or personal stories, links to the items you select will be saved in this area for as | long as you choose to keep them there. All you have to do | | In addition, you can type in personal notes along with the | items you save. We will not access, use, or review your personal notes for any reason. | ou'd like to go directly to one of the five sections, select | | | | not show this page again. |
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| Search clinical trials | Home / Knowledge Center | Welcome | Here's vou | Library is w | found throu | perspective links to the | long as you | the site. | In addition, | items you s personal n | If you'd like to | Drug InformationClinical Trials | ② Ask The E | Feature Stories | ☐ Do not sho |
| Search | | | © Feature Stories | | Ask the Expert | About Clinical Trials | | Therapeutic Area | | Neurological Conditions | | © Register Now Review Clinical | Trials Ask | Questions and More | |

FIG 6B

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FIG. 7A

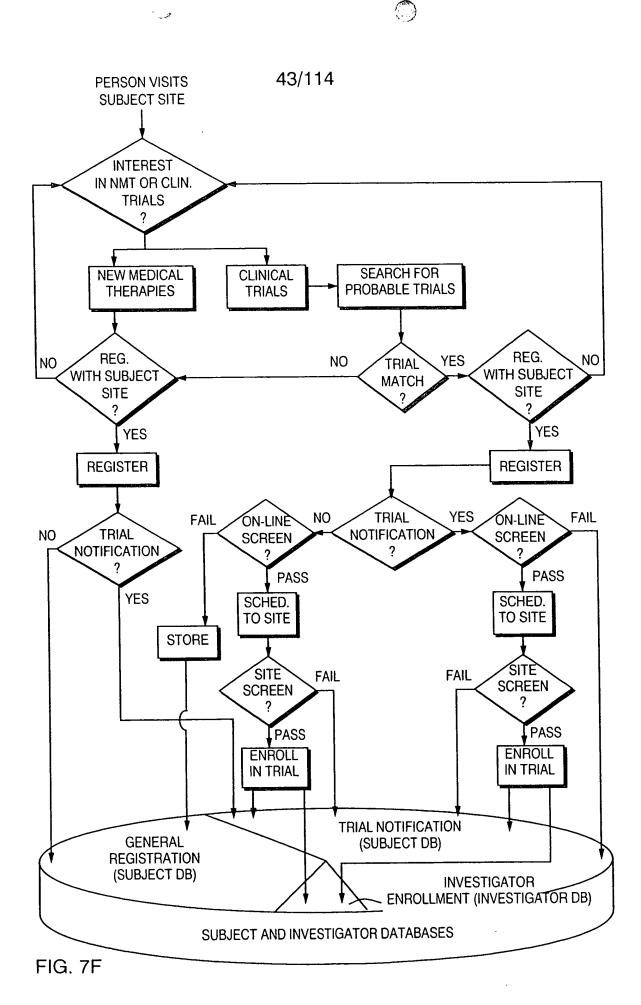
704 902: 705 703 Phase IV Phase II % ○ % O ջ 0 Phase III Phase I Select One Sey C Yes Yes Yes Phone (with area code) * Zip Code/Postal Code * Investigator has participated in trials?* Board Certification(s) * which the Investigator Indicate all phases of Telephone Extension Board Certification(s) Fax (with area code) Year of Certification Year of Certification Primary Specialty * clinical research in Number of years Board Eligible * Email Address **Board Eligible** Sub Specialty participated *

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| Investigators | Local IRB 🔲 Centra IEC (Canadian sites only) | | Weekly Monthly Other | | | O Yes O No |
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| How many Investigators conduct research at this PRF?* | Is the Investigator affiliated with: (check all that apply) | If affiliated with a local IRB, what is its name? | How often does the local IRB meet? | If "other", frequency of local IRB meeting? | How soon after the IRB meeting will you receive an approval letter? | Has the Investigator ever been audited by the Food & Drug Administration (FDA) or any other regulatory agency? |

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| If yes, what was the date of the audit? | Who was the auditor? | If audited, was a 483 issued? | What were the results of the audit? | If yes, what was the date of the audit? | Who was the auditor? | If audited, was a 483 issued ? | What were the results of the audit? | Has the Investigator gone through an audit by a sponsor or CRO? | If yes, what was the date of the audit? | Who was the auditor? |

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| | | | | ☐ Single specialty☐ Multi-specialty | | | □ Solo practice□ Group practice | O Yes O No | | O Yes O No | Save and Continue |
| What were the results of the audit? | 2. If yes, what was the date of the audit? | Who was the auditor? | What were the results of the audit? | ls your PRF | If PRF is multi-specialty, indicate specialties. (one per line) | | Is your facility part of | Is the facility affiliated with a Site Management Organization (SMO) or research group? | If affiliated, please specify the SMO name | If affiliated, is this an exclusive relationship? | © Cancel |





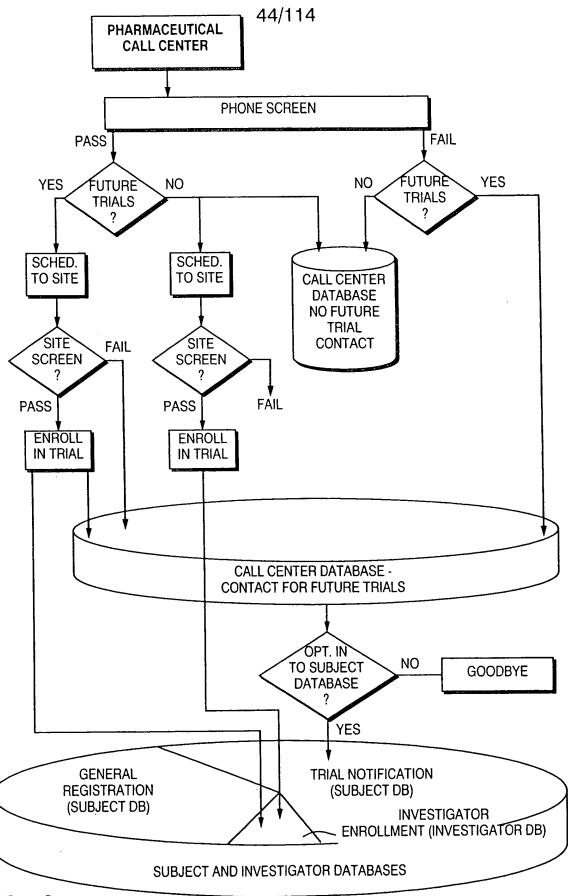
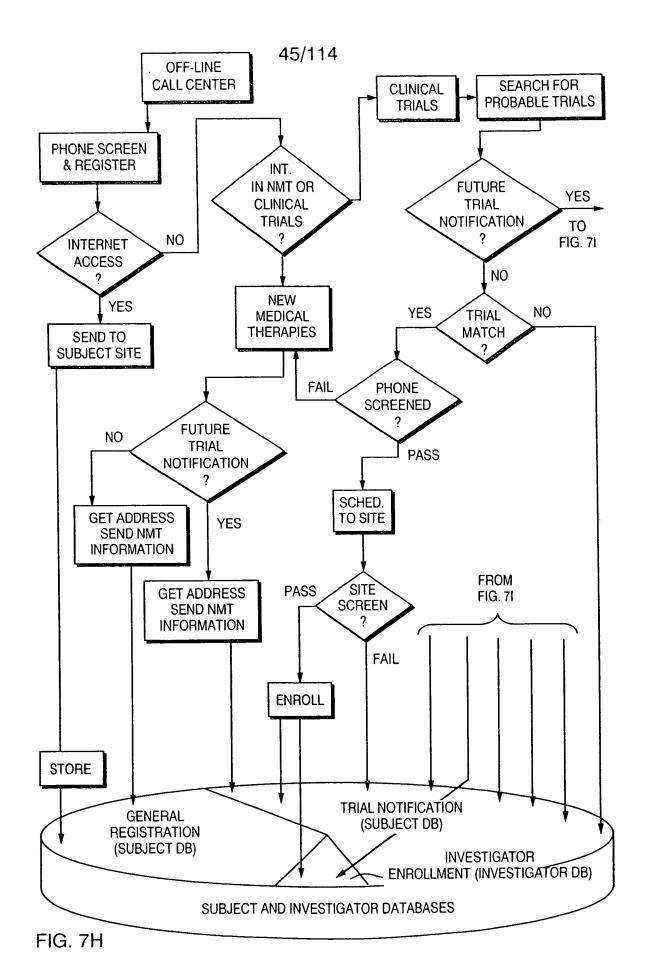


FIG. 7G





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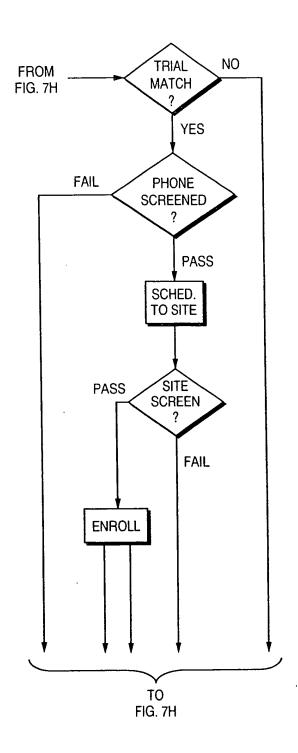


FIG. 71



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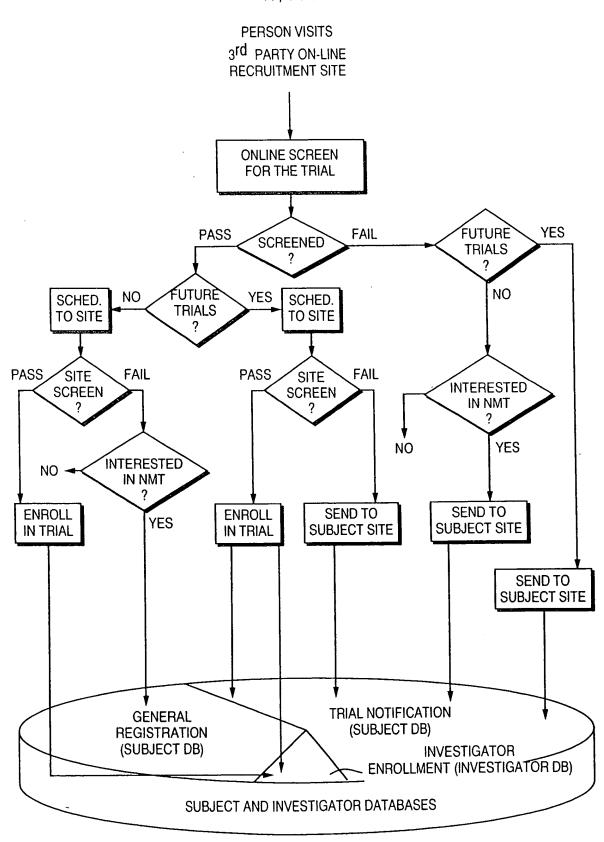


FIG. 7J

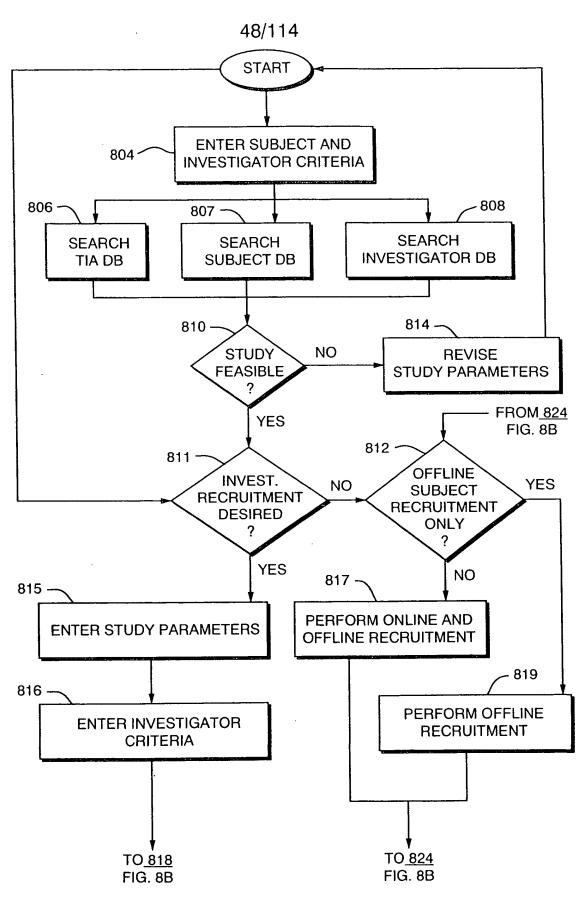


FIG. 8A



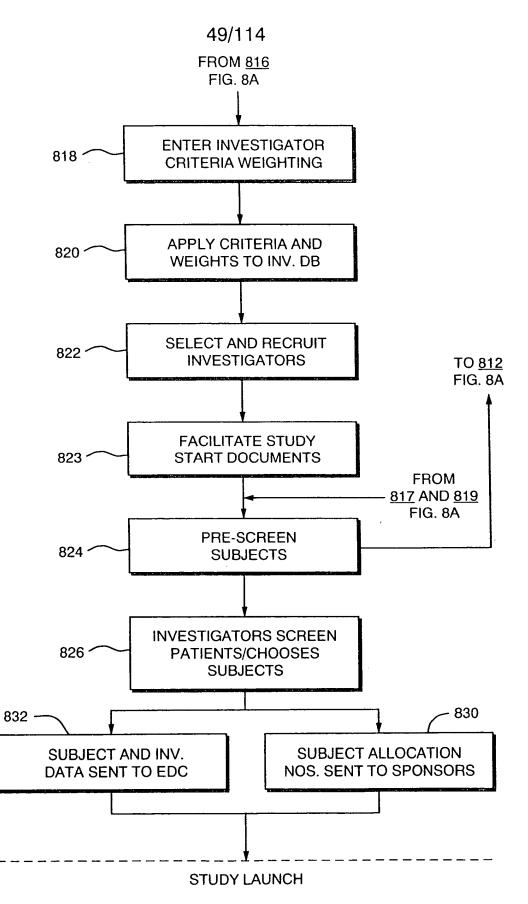
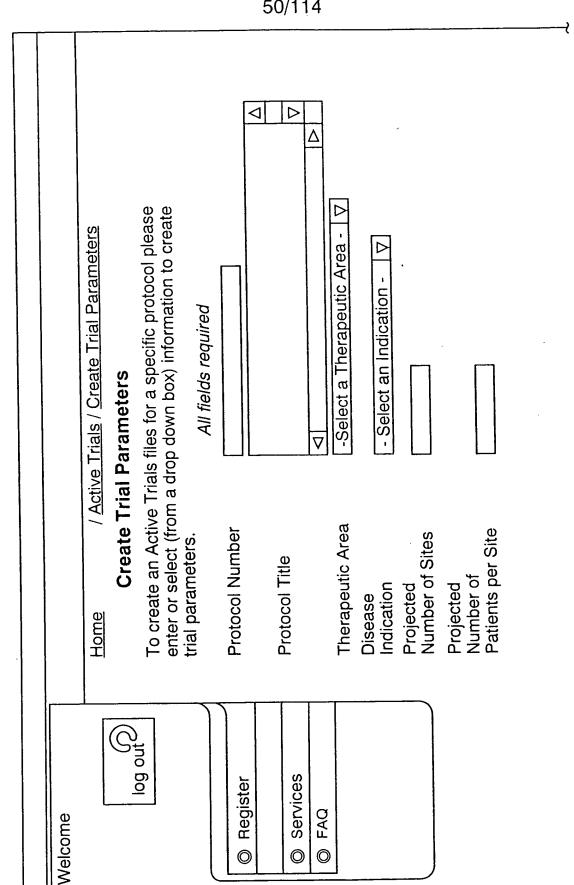


FIG. 8B



CASILLES CALCEL

FIG. 9A

CATHUMES . GEGE

FIG. 9B

To identify potential investigators - please select a specialty.

Step 1:

Allergy & Immunology Adolescent Medicine Aerospace Medicine Addiction Psychiatry

Note: To select more than one specialty, point to the specialty and press control click. Limit of 2 selections.

To include the prescribing behavior data in the investigator search results class relevant to the therapeutic area and indication. (optional)

Step 2:

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All Other Misc. Ethical Drugs - No Drug Class Aids Therapies Acne Therapy

Note: To select more than one specialty, point to the specialty and press control click. Limit of 2 selections.

To include the number of trials conducted by the investigator in the search, enter a number. (optional)

Step 3:



To access additional databases to enhance the investigator selection process, enter selections below. (optional)

Step 4:

CASE SE SESE

Patient Therapeutic Area



Patient Disease Indication



Patient Disease Indication Encounter Category

Case Load Estimates - Malignancy of heptobiliary system of pancreas Inpatient Discharge Diagnosis - Malignant neoplasm of pancreas - Select a Category -

point to the specialty and press control click. Limit of 2 selections. patient disease encounter category, Note: To select more than one

Patient Distance from Site (in miles)



To limit search by geographical location - please enter your selections below.

Municipal Area

Step 5:



FIG. 10B

| The following investigator search and the patient demographic data selections by scrolling down this protections by scrolling down this protection by scrolling down this protection by scrolling down this protections by scrolling down this protection by scrolling down t | Investigator Search Results investigator search results reflect the transport data selected in the list of scrolling down this page or by clicking. Click a column heading to sort the part of 682 results | nvestigator Search Results | | _ |
|--|--|--|---|---------------|
| | investigator search resit t demographic data sel scrolling down this pagesary. Click a column head on the selection of 682 results | | | |
| Register Services FAQ Security & Privacy Policy Active Trials | of 680 recults | The following investigator search results reflect the investigator search criteria and the patient demographic data selected in the Investigator Search. Review selections by scrolling down this page or by clicking here: Investigator Search Criteria Summary. Click a column heading to sort by that column. | or search criteria Search. Review estigator Search mn. | |
| Search Rones, Jones, Jones, Jones, Jones, Jeach Fagaservices FAQ Schelker, Tucker, Jecker, Jecker, Jecker, Michelson, Rieger, Boe, Jective Trials Greene, Manne Jone, Jective Trials Greene, Manne Jones, Jective Tria | ייישפטן אסט וט pad וס | Total | | |
| Services Services FAQ Security & Michelson, Michelson, Michelson, Michelson, Kleger, Boo, Joe, Joe, Jennials Security & Michelson, Kleger, Boo, Jennials Security & Michelson, Michelson, Kleger, Boo, Jennials Greene, Michelson, Mich | lts: | | | |
| Services Jones, J FAQ Turco, C Schelker, J Tucker, J Schelker, J Tucker, J Robinson, Michelson, Kleger, B Doe, J Active Trials Greene, M | Specialty | City, State | \$ 25 | |
| FAQ Schelker, Schelker, Jucker, Jucker, Jucker, Jucker, Jucker, Jucker, Jucker, Jucker, Michelson, Michelson, Kleger, Boe, Jucker, Smith, Suith, Suit | Cardiovascular Disease Cardiovascular Disease | SEALILE, WA LA JOLLA, CA | 23 28 | 54/ |
| Tucker, J Tucker, J Robinson, Michelson, Kleger, B Doe, J Smith, S Greene, M | Cardiovascular Disease | SALT LAKE CI, UI MILWAUKEE, WI | 27 | 1114 |
| licy Michelson, Michelson, Michelson, Kleger, B Doe, J Smith, S Is Greene, M | | CINCINNATI, OH | 25 | 1 |
| | Cardiovascular Disease Cardiovascular Disease | OKLAHOMA CIT, OK | 24 | |
| | Cardiovascular Disease | PITTSBURGH, PA SARASOTA, FL | 22 20 20 | |
| | | HILLSBORO, OR | 100 | |
| ☐ Create Trial Watson T | Cardiovascular Disease Cardiovascular Disease | FOX FOINT, WI FORT WAYNE, IN | 17 | |
| | | BALTIMORE, MD | 16 | • |
| Hamilton, P Tang, H | Cardiovascular Disease Cardiovascular Disease | REDONDO BEAC, CA | 22.0 | |
| Wilcox, J | Cardiovascular Disease | PEORIA, IL SANTA ROSA, CA | 13.3 | (|
| Restrepo, A | Cardiovascular Disease | CHARLESTON, SC | 13 | 10 FIG 11B |
| Grossman, D | Cardiovascular Disease | SELLERSVILLE, PA | 12 |) - - |

Misc Other 6 RB any document to go to Document View by Investigator. Click on Summary of document status for the selected protocol. Click on Other 5 any investigator to go to specific Investigator Document View. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of | Regulatory | Financial | Vendor Info | CV/Signature Other A multi-center study ... Document Summary Other 3 Trial at a Glance Other 2 Other Trial Synopsis Conf. Agreement Active Trials / documents in that category. Questionnaire ဟ ဟ **Document Tracking** S = Sent R = Received C = Completed Robinson, M. Feasibility | nvestigator egend Smith, J. Home Investigator Protocol Number Document Document Summary Services Register View View FAQ Welcome 345678 0 0 0 0 0 0

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FIG. 12

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Investigators:

Return to Trial at a Glance

0

Regulatory | Financial | Vendor Info | CV/Signature | IRB | Misc Create New Document categories denoted by the tabs below. Click on a tab to view status of the drop down box. Study launch documents have been grouped into investigator to go to document history of the document selected in Active Trials / Trial at a Glance / Document Completed 1/28/01 $Z \land X \land X \land A \land L$ Date Summary of document status by investigator. Click on any Document View by Investigator \triangleright ഗ 1/27/01 Rec'd Date Tracking / Document View by Investigator α Ø ۵ 0 z S documents in that category エーンドト Questionnaire Date Sent ഗ ட Investigators: ABCDEI Document: Feasibility | Investigator ABCD Smith, J. Home / Investigator Protocol Number Document Document Summary Services Register View View FAQ Welcome 345678 0 0 0 0 0 0

COMMUNICATION

FIG. 13

From: Service Provider

Sent: June 6, 2000

To: Ms. Moore

Subject: Clinical Trial Opportunity

Dear Ms. Moore:

You may qualify for an upcoming clinical trial opportunity. For additional information go to http://www.website.com/study/zz-234567-22* and complete the study specific questionnaire.

Contact service.com with any questions or comments you may have.

Sincerely,

Service Provider

If you have received this message in error or no longer would like to be considered or contacted about clinical trials please go to http://www.service.com/remove

FIG. 14

CANTARD CACACH

Questionnaire - Alzheimer's

In order to evaluate whether you may be eligible for this study, we will need to review some of your medical history. Are you legally able to provide us with this information for the potential study participant?

Yes, I am the potential study participant.

Yes, I am a caregiver for the potential study participant with the ability to provide the potential participant's information for the purpose of seeking enrollment in clinical studies.

No, I am not legally able to provide this information.

In answering the following questions, "you" or "your" refers at all times to the potential study participant.

Please provide your gender.

- O Male O Female

How did you hear about this study? O Internet

- Newspaper Ad
- Newspaper Article
- Radio Public Service Announcement Radio Ad
- TV Ad
- TV program
 - Physician
 - Friend
- Support Group
- Cardiology Newsletter Patient Ed Materials

 - Other, please specify:

daily visits from a responsible caregiver. The caregiver must be familiar with your recent medical the ability to reason, remember, imagine, and learn in humans who have already been diagnosed The purpose of this medical research study is to evaluate the effect of an investigational drug on with mild to moderate probable Alzheimer's Disease. You must live with a caregiver or receive history and be willing to come to 7 doctor visits for a period of 6 months.

COSELUCE LOGINAL

person at the research facility will be calling you. At that time, it will be determined if a first After these questions are answered we may be able to refer you to a research site for further screening. After the site reviews your responses to the screening questions, a nurse or other visit should be scheduled to determine whether this study is appropriate for you.

Have you been diagnosed with Alzheimer's disease?

Have you experienced a deterioration in memory over at least the last 6 months?

Click the box next to the following if you have experienced a decline in any of the following in at least the last 6 months:

- O orientation
- judgement
- problem solving
- functioning in community affairs functioning in home or hobbies
 - functioning in personal care

(3)

| Do you live in a residential home ? O Yes O No | Click the box next to the person who will serve in the role of Caregiver: I am the Caregiver Friend Relative Paid personnel No Caregiver | 1. Please enter your date of birth: | Day Month Year (pull-down boxes) | ☐ If female, continue with question 2 ☐ If male, continue with question 6 | 2. Are you/Is (Patient) surgically sterile or post-menopausal for 1 year or more? | O Yes - continue with question #6 O No - continue with question #3 | 3. Do you/Does (Patient) have any other neurological conditions such as: | O Parkinson's disease O Pick's disease O Huntingtons chorea O Down's syndrome O Creutzfeldt-Jacob disease |
|--|---|-------------------------------------|----------------------------------|---|---|--|--|---|
|--|---|-------------------------------------|----------------------------------|---|---|--|--|---|

| 4. Do you now or did you at any time, have one or more of the following conditions | resulting in your memory or cognitive impairment: |
|--|---|
| 4. | |

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| ' | _ | , |

| O Injury caused by tra O Vitamin deficiency | Injury caused by trauma such as boxing Vitamin deficiency |
|--|---|
|--|---|

O Type (drop down menu)

- O Brain abscess
 - Syphilis
- Brain cancer
- Thyroid, parathyroid, or pituitary disease O Meningitis O AIDS O Brain cancer O Thyroid, par

- O Cushing's syndrome
 O Kidney failure
 O Uncontrolled diabetes
 O Mental retardation
- Do you have a history of any of the following: Ś.
- O Stroke within the past 12 months
 O Epilepsy or convulsions (Childhood convulsions caused by fever continue)
 O Major depression
 O Stomach ulcer that is currently being treated
 O Liver, kidney, or lung disease
 O Kidney stones
- - Kidney stones
- Have you had a heart attack or coronary artery bypass graft surgery within the past 6 months? 6.
- OO Yes

Do you experience angina (chest pain) that required a change in medication in the past 3 months? 7.

O Yes O No

Has a doctor told you that you have a heart rate that is slow or less than 50 beats per minute? ∞:

O Yes O No

Do you take medication for high blood pressure or chronic low blood pressure?

O Yes

O Medication(s) taken: (drop down menu) 6

O No O Don't know

10. Do you take any medications for the purpose of treating memory loss such as dementia?

O Yes

11. Are you allergic to any medications?

O Yes O Which Medication(s) (drop down menu)

°Z O

Are you taking any other medications including vitamins or herbal supplements such as Ginkgo Biloba? 12.

CSSELEGU CECEL

O Yes O Which Medication(s) (drop down menu)

Have you ever been enrolled in a research study for galantamine? 13.

E)

O Yes O No O Don't know

Have you taken an investigational drug in the past 30 days or are you taking one now? 14.

O No, I have not taken an investigational drug in the past 30 days

O Yes, I have taken an investigational drug in the past 30 days O Yes, I am taking an investigational drug now

How many drinks do you consume in a typical 24-hour period? 15.

O 1-2 drinks
O 3-5 drinks
O 6-8 drinks
O more than 8 drinks

Have you/patient had a CT scan or MRI of the head during the last 12 months? 16.

O Yes O No

Questionnaire - Alzheimer's

PATIENT NOT ELIGIBLE FOR STUDY SCREEN #2:

provided, you are not a candidate for participation in this study. May we have your permission to contact you in the future with information about this or other studies? We appreciate your interest in this study. Unfortunately, from the information you have

O Yes, contact me. O No, I do not want to be contacted.

FIG. 15G



Questionnaire - Alzheimer's

PATIENT POTENTIALLY ELIGIBLE FOR STUDY: SCREEN #3:

information to the research site you selected. The research site will contact you shortly to ask you further questions about your health, and possibly to schedule an appointment for the first visit. In the meantime, we will send you a Welcome Kit that contains information about the study. If the site does not contact you within 5-7 business days, please feel free to call the Based on your responses, you may be eligible for the clinical study. We will forward this number that will be included in your mailed materials.

In the event that you do not participate in this particular study, may we have your permission to contact you in the future about other studies?

- O Yes, contact me O No, I do not want to be contacted

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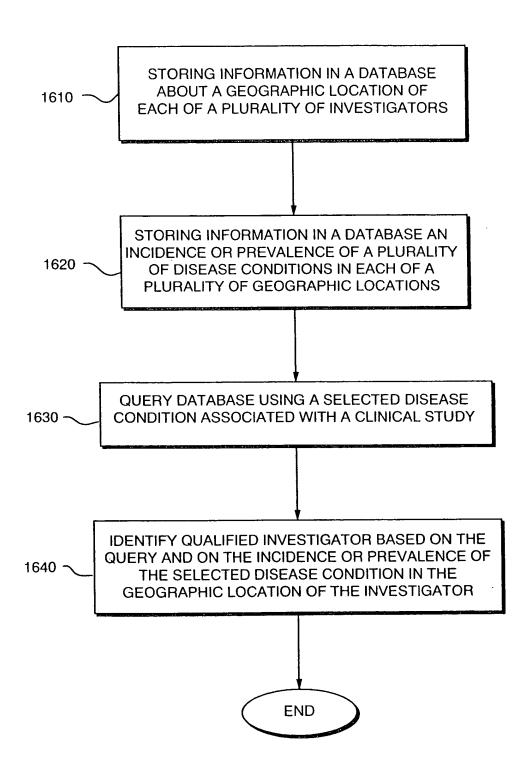


FIG. 16



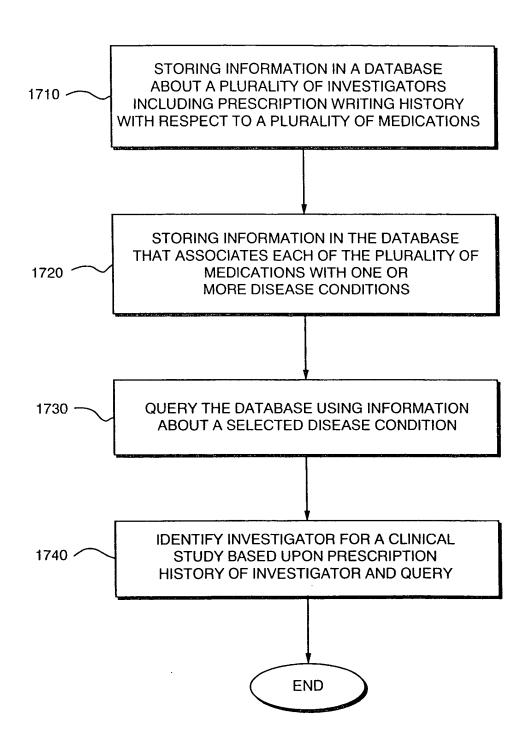


FIG. 17

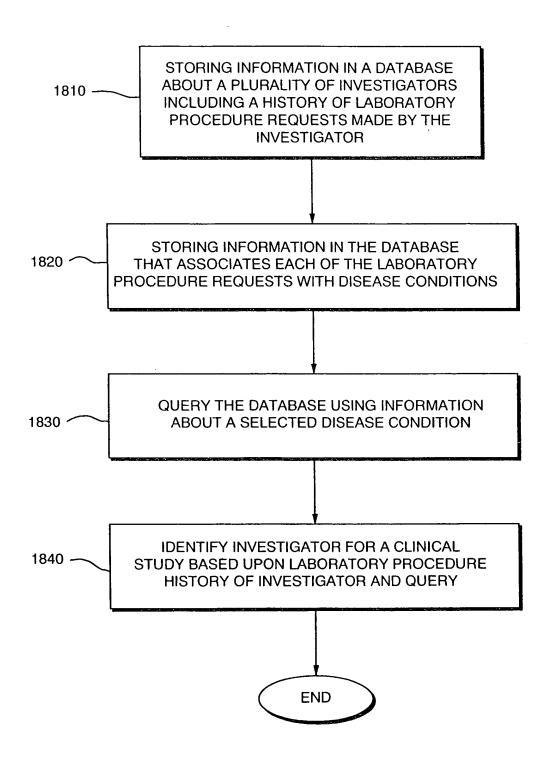


FIG. 18

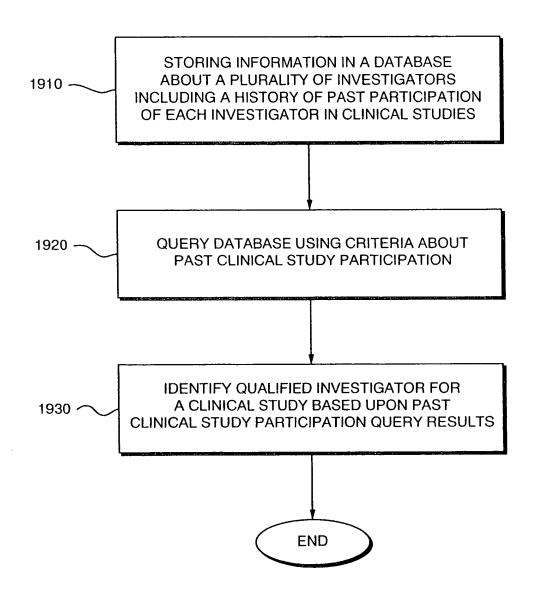
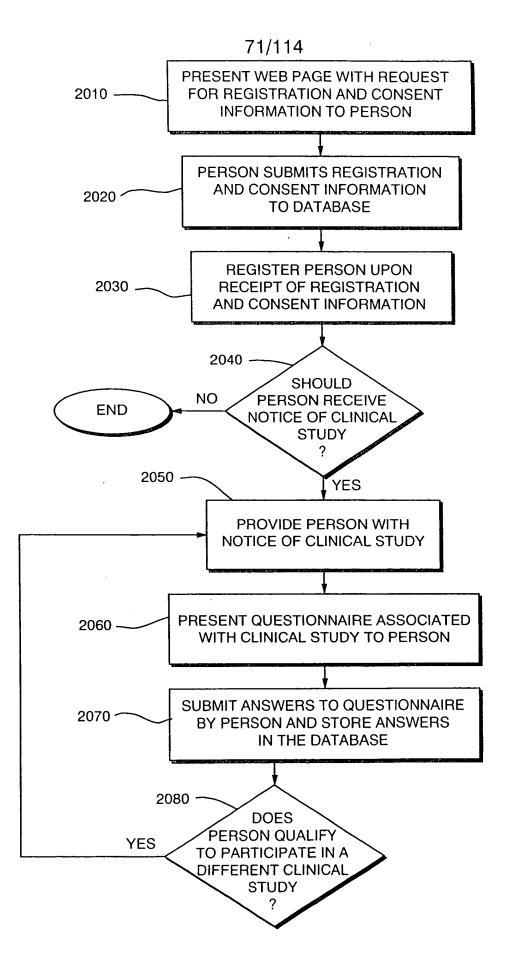


FIG. 19



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FIG. 20



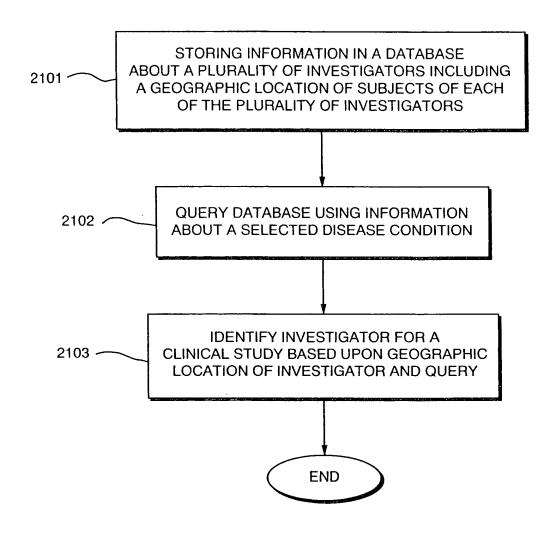


FIG. 21A

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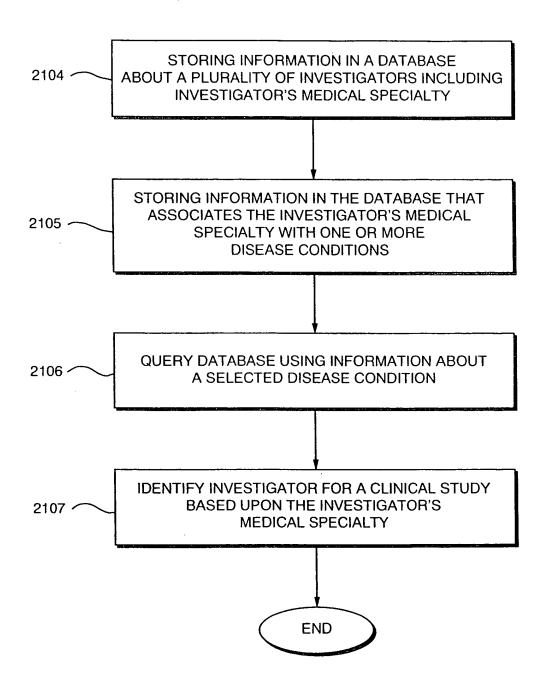


FIG. 21B



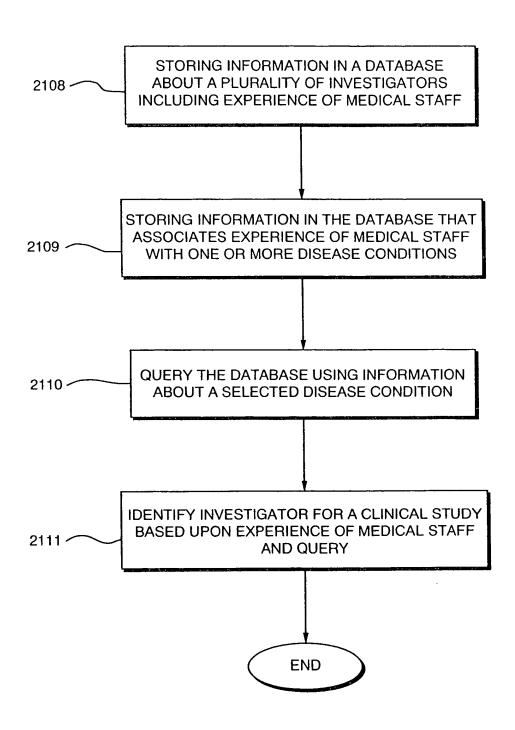


FIG. 21C



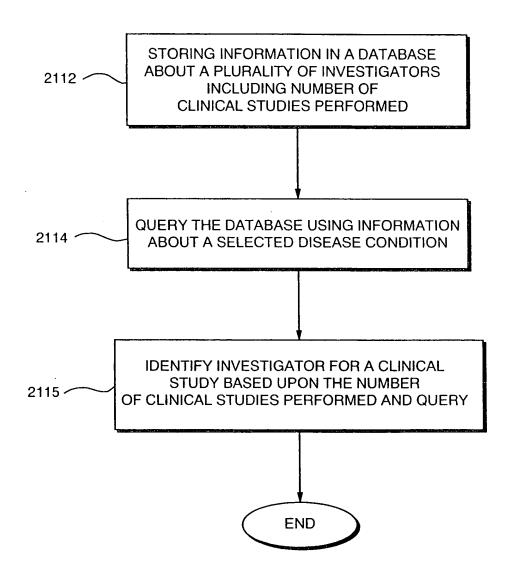


FIG. 21D



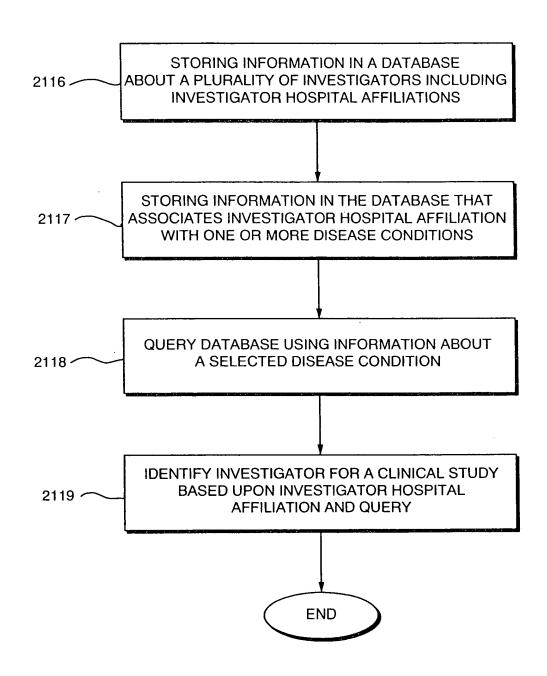


FIG. 21E



2 30

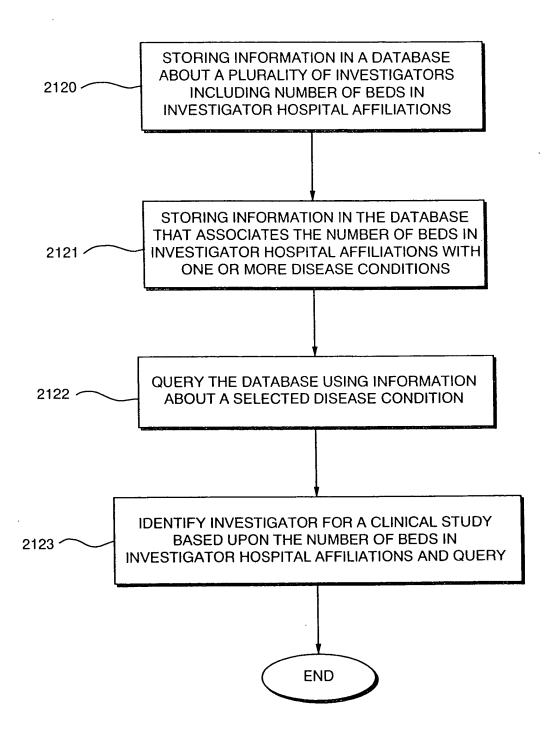


FIG. 21F

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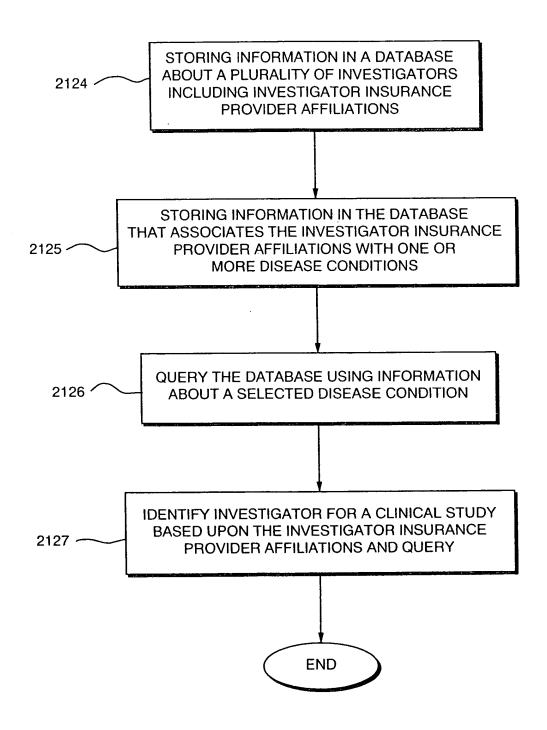


FIG. 21G



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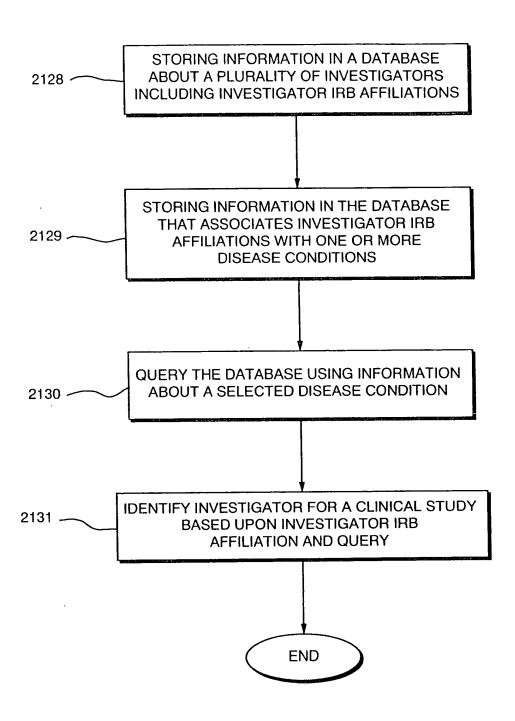


FIG. 21H



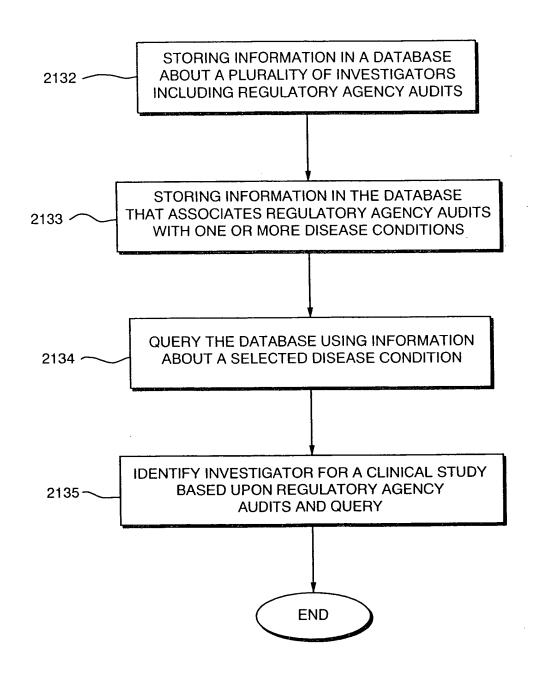


FIG. 211

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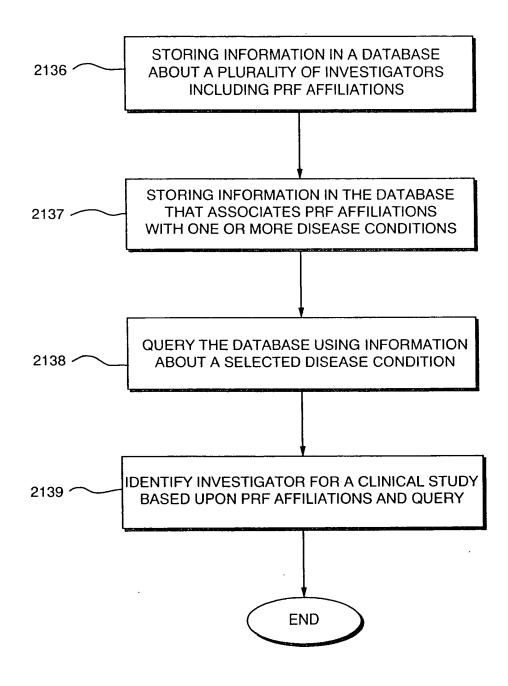


FIG. 21J



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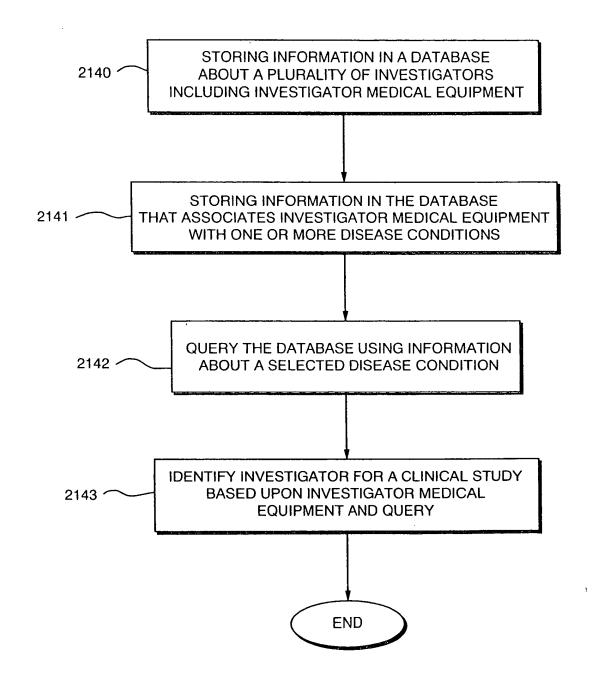


FIG. 21K



5.307

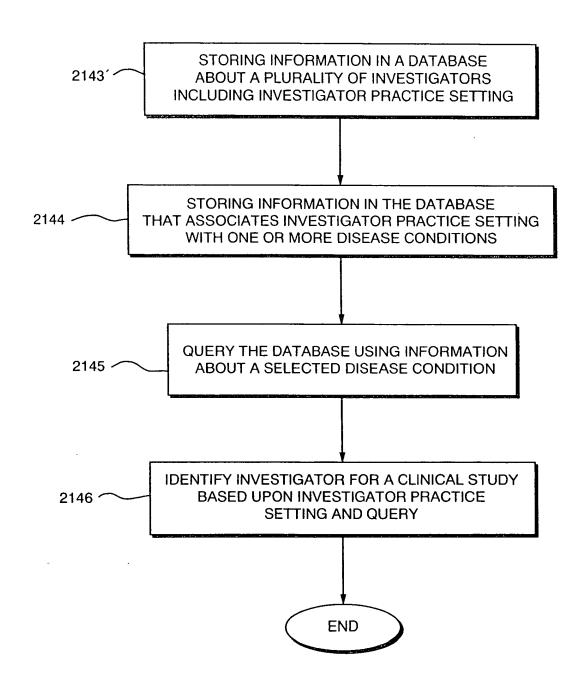


FIG. 21L

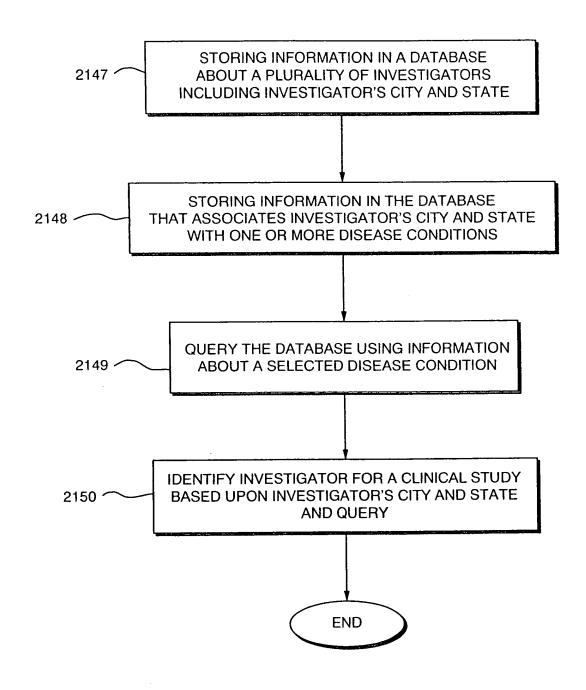


FIG. 21M

Contract of the second

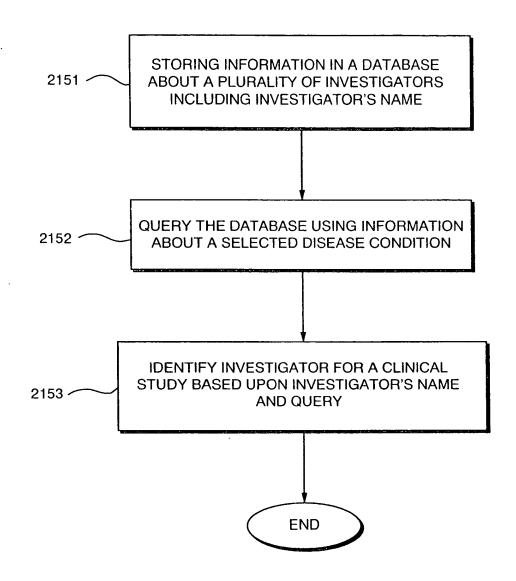


FIG. 21N

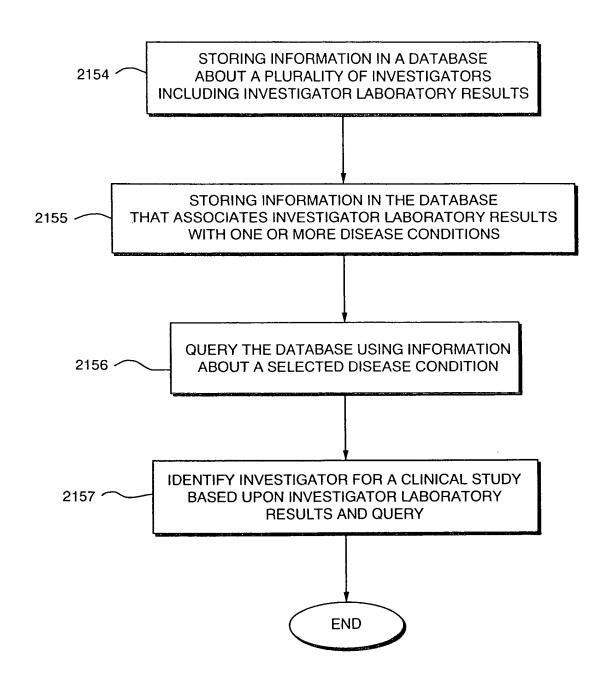


FIG. 210

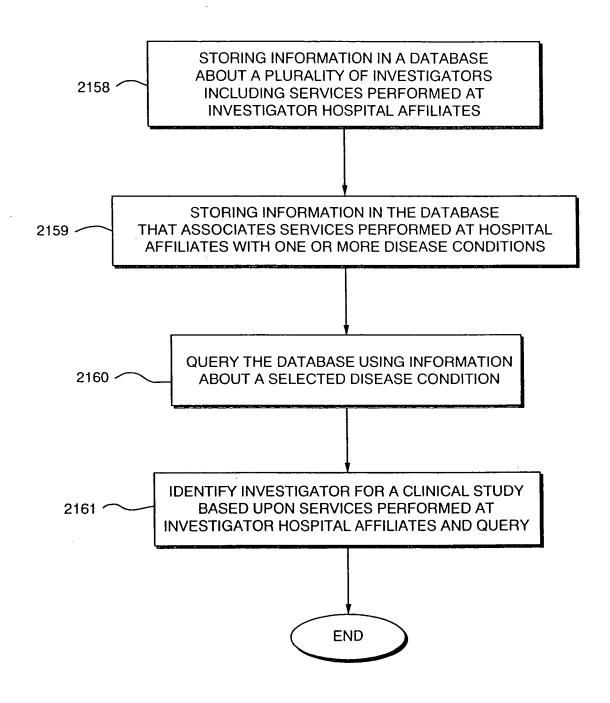


FIG. 21P

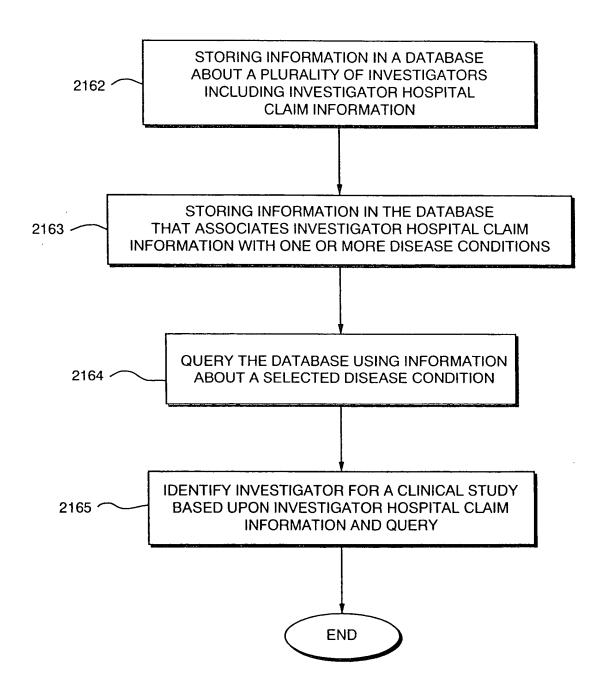
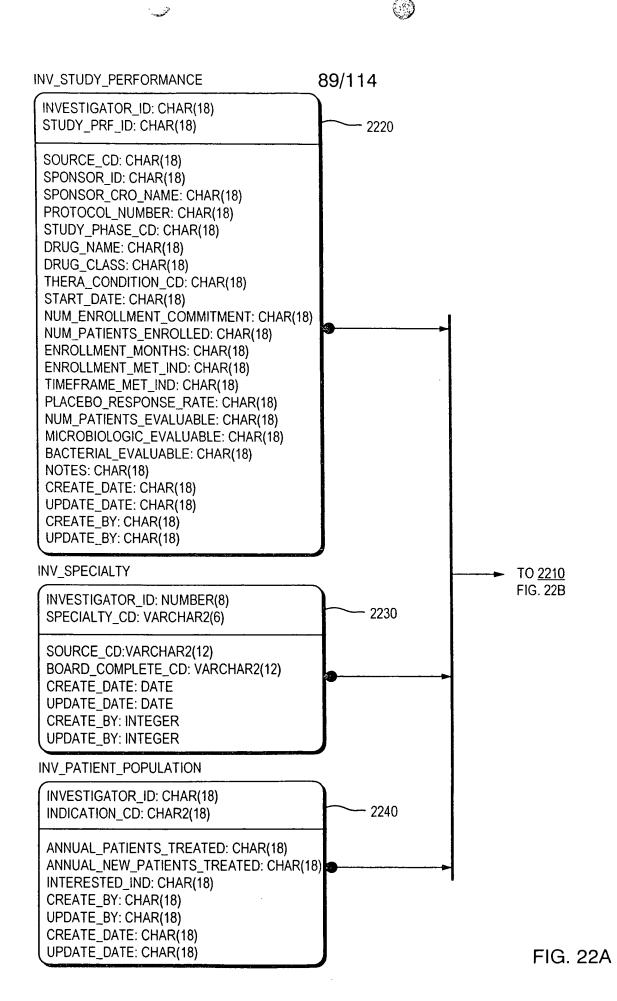
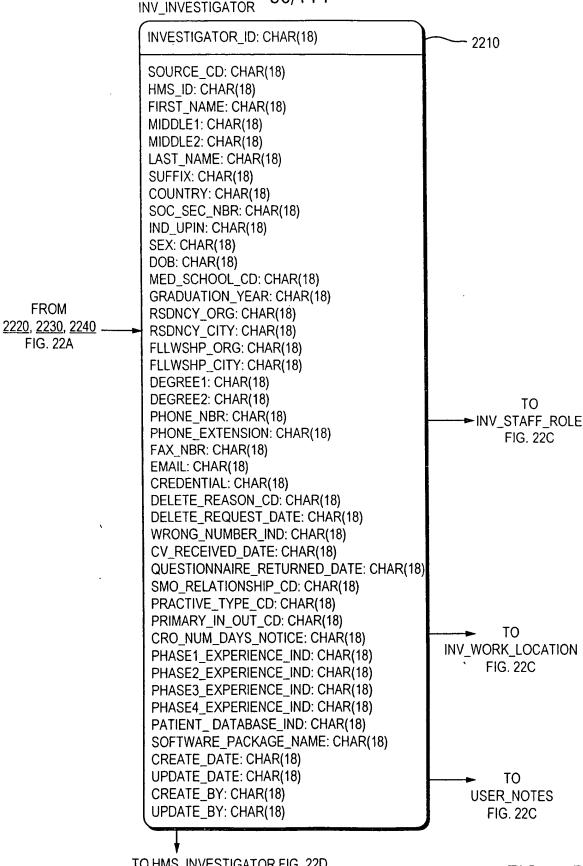


FIG. 21Q



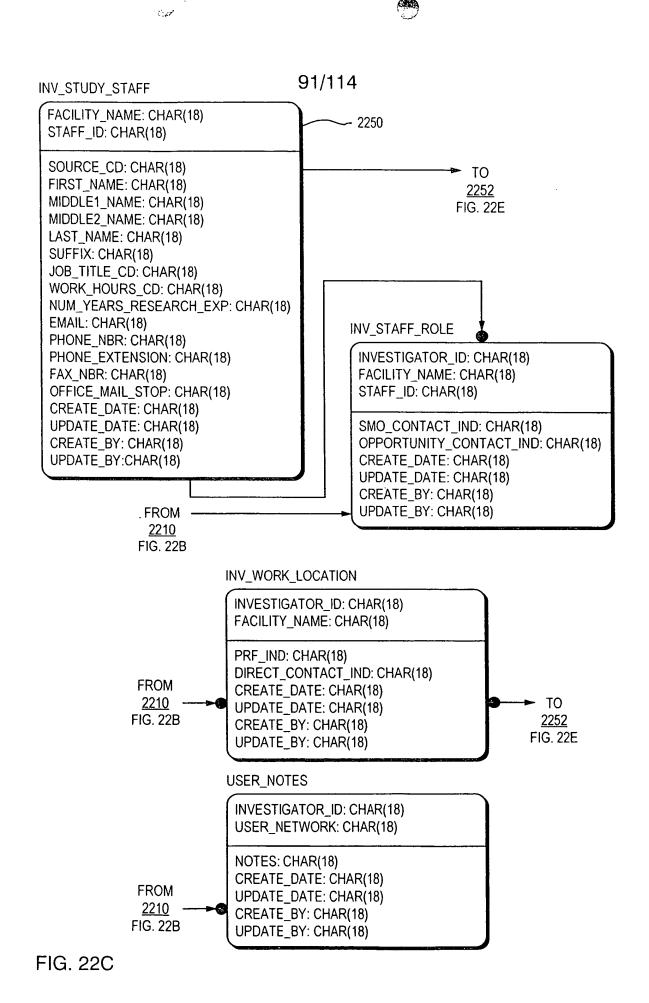


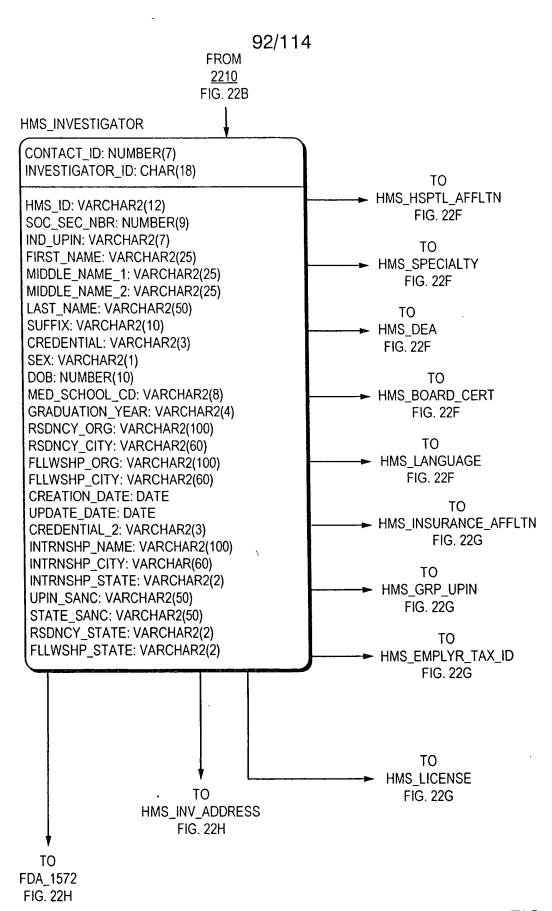




TO HMS INVESTIGATOR FIG. 22D

FIG. 22B







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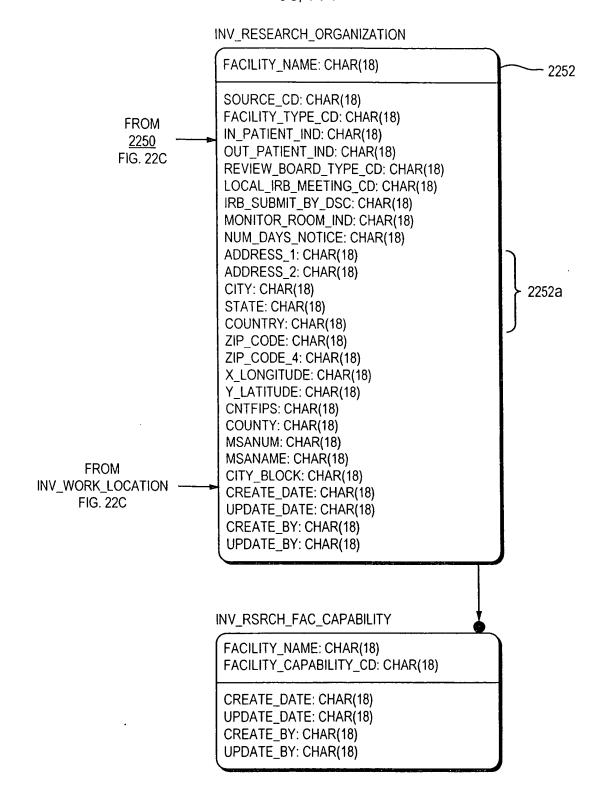


FIG. 22E

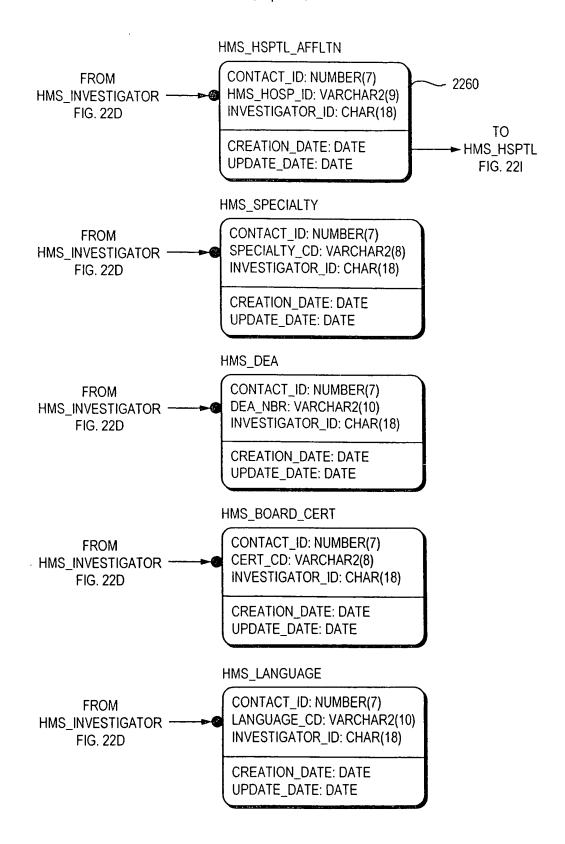
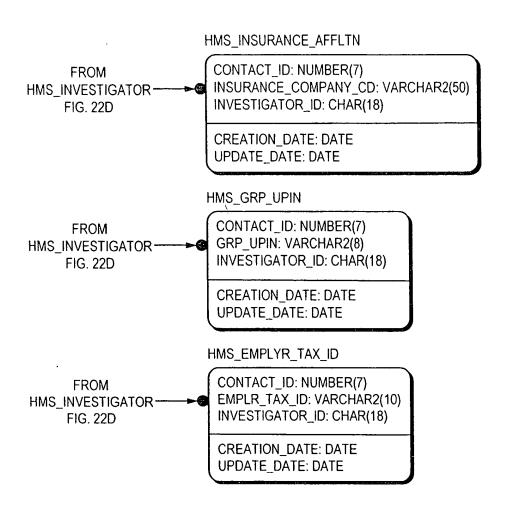


FIG. 22F

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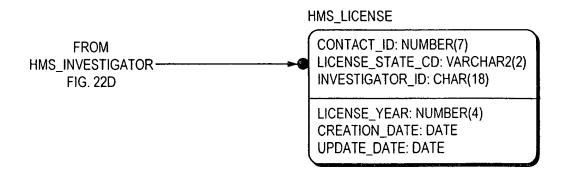


FIG. 22G



FROM HMS INVESTIGATOR

FIG. 22D

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FROM HMS_INVESTIGATOR FIG. 22D

FDA 1572

CONTACT ID: NUMBER(7) FDA_1572_ID: NUMBER(7) INVESTIGATOR_ID: CHAR(18)

HMS_ID: VARCHAR2(12) LAST NAME: VARCHAR2(100) FIRST_NAME: VARCHAR2(25) MIDDLE_INITIAL: VARCHAR2(1) SUFX: VARCHAR2(5) CRED1: VARCHAR2(8) ORGNAME: VARCHAR2(100) ADDRESS: VARCHAR2(100)

CITY: VARCHAR2(35) STATE: VARCHAR2(2) ZIP_CODE: NUMBER(14) COUNTRY: VARCHAR2(60)

YEAR: NUMBER(4) RECEIPT_DATE: DATE

RECEIPT_YEAR: NUMBER(4) ORG_TYPE: VARCHAR2(3) CREATION DATE: DATE

HMS INV ADDRESS

CONTACT_ID: NUMBER(7) ADDRESS ID: NUMBER(6) INVESTIGATOR_ID: CHAR(18)

HMS_ID: VARCHAR2(12)

TIER: NUMBER(3)

FIRM_NAME: VARCHAR2(100) ADDRESS_1: VARCHAR2(75) ADDRESS_2: VARCHAR2(75) PHONE_NBR: NUMBER(15) FAX_NBR: NUMBER(15) CITY: VARCHAR2(35) STATE: VARCHAR2(2) ZIP_CODE: NUMBER(10) ZIP CODE 4: NUMBER(4) X LONGITUDE: NUMBER(15) Y_LATITUDE: NUMBER(15) MSANUM: NUMBER(12) MSANAME: VARCHAR2(45)

CNTFIPS: NUMBER(12) CITY_BLOCK: VARCHAR2(30) CREATION_DATE: DATE

COUNTY: VARCHAR2(30)

UPDATE_DATE: DATE

FDA 483

CONTACT_ID: NUMBER(7) FDA_DFCNCY_ID: NUMBER(8) CONTACT_ID: NUMBER(7) INVESTIGATOR_ID: CHAR(18)

HMS_ID: VARCHAR2(12) LAST_NAME: VARCHAR2(100) FIRST_NAME: VARCHAR2(25)

ORG: VARCHAR2(100) ADDRESS: VARCHAR2(100)

CITY: VARCHAR2(35) STATE: VARCHAR2(2) ZIP_CODE: NUMBER(14) COUNTRY: VARCHAR2(60) INSPCTN_DATE: DATE

CLSSFCTN_TYP: VARCHAR2(2) CLSSFCTN_CD: VARCHAR2(5) DFCNCY_CD: NUMBER(2) CREATION_DATE: DATE

FDA_1572_STAT

CONTACT ID: NUMBER(8) **INVESTIGATOR ID: CHAR(18)**

NUM_TRIALS_LAST5: INTEGER NUM_TRIALS_LAST4: INTEGER NUM_TRIALS_LAST3: INTEGER NUM_TRIALS_LAST2: INTEGER NUM TRIALS LAST1: INTEGER TOTAL_TRIALS_LIFETIME: INTEGER

FIRST YEAR: INTEGER LAST_YEAR: INTEGER UPDATE_DATE: DATE

FIG. 22H



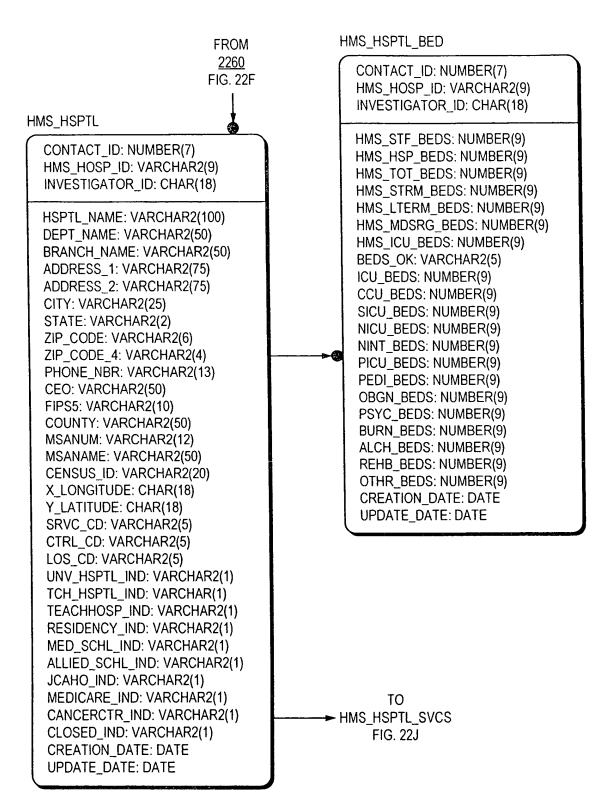


FIG. 221



HMS HSPTL_SVCS

CONTACT_ID: NUMBER(7) HMS_HOSP_ID: VARCHAR2(9) INVESTIGATOR_ID: CHAR(18)

AIDS_SVCS: VARCHAR2(1) ANSTH_SVCS: VARCHAR2(1) ANGPLSTY_SVCS: VARCHAR(1) BLOODBNK_SVCS: VARCHAR(1) BMTRNSPL_SVCS: VARCHAR2(1) BURNCTR_SVCS: VARCHAR2(1) CRDCTH_SVCS: VARCHAR2(1) CVSRGY SVCS: VARCHAR2(1) CHIRO_SVCS: VARCHAR2(1) CLPSY_SVCS: VARCHAR2(1) CT SVCS: VARCHAR2(1) DENTL_SVCS: VARCHAR2(1) ULTRSND_SVCS: VARCHA2R(1)

FROM HMS_HSPTL · FIG. 221

DIETRTY_SVCS: VARCHAR2(1) ECARD SVCS: VARCHAR2(1) ECONV_SVCS: VARCHAR2(1) **EMRGCY SVCS: VARCHAR2(1)** ESWL_SVCS: VARCHAR2(1) LABAN_SVCS: VARCHAR2(1) HEART_SVCS: VARCHAR2(1) HRTLUNG_SVCS: VARCHAR2(1) HEMDIAL_SVCS: VARCHAR2(1) HOMCRE_SVCS: VARCHAR2(1) HOSPCE_SVCS: VARCHAR2(1) CCU_SVCS: VARCHAR2(1) ICU_SVCS: VARCHAR2(1) KIDNEY SVCS: VARCHAR2(1) LABCLNC_SVCS: VARCHAR2(1) LIVER_SVCS: VARCHAR2(1) LUNG SVCS: VARCHAR2(1) MEGVRAD_SVCS: VARCHAR2(1) NEONUNT_SVCS: VARCHAR2(1) NICU SVCS: VARCHAR2(1) MRI_SVCS: VARCHAR2(1) **NEURO SVCS: VARCHAR2(1)** NSURG_SVCS: VARCHAR2(1) NUCMED_SVCS: VARCHAR2(1) **OBSRVA SVCS: VARCHAR2(1) OBSTE SVCS: VARCHAR2(1)** OCCTH_SVCS: VARCHAR2(1) OPNHT SVCS: VARCHAR2(1)

TO FIG. 22K

HMS_HSPTL_SVCS (CONT'D)

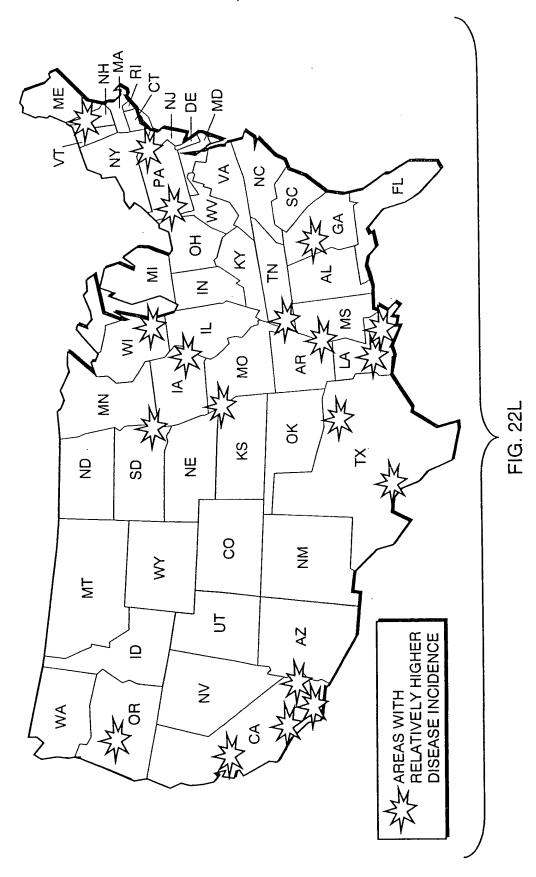
FROM FIG. 22J

OPTOM_SVCS: VARCHAR2(1) ORGBANK_SVCS: VARCHAR2(1) ORGAN_SVCS: VARCHAR2(1) OUTPAT_SVCS: VARCHAR2(1) OUTSRG_SVCS: VARCHAR2(1) PANCR_SVCS: VARCHAR2(1) PEDIAT_SVCS: VARCHAR2(1) PHARM_SVCS: VARCHAR2(1) PHYTH SVCS: VARCHAR2(1) PSTOP_SVCS: VARCHAR2(1) PSYED SVCS: VARCHAR2(1) PULMON_SVCS: VARCHAR2(1) RADIM_SVCS: VARCHAR2(1) RECTH_SVCS: VARCHAR2(1) REHAB_SVCS: VARCHAR2(1) RESPIR_SVCS: VARCHAR2(1) SELFCARE_SVCS: VARCHAR2(1) SKNLT_SVCS: VARCHAR2(1) SOCSVC_SVCS: VARCHAR2(1) SPEECH_SVCS: VARCHAR2(1) THERD_SVCS: VARCHAR2(1) TRAUMA_SVCS: VARCHAR2(1) XRADT_SVCS: VARCHAR2(1) CREATION_DATE: DATE UPDATE_DATE: DATE

FIG. 22K







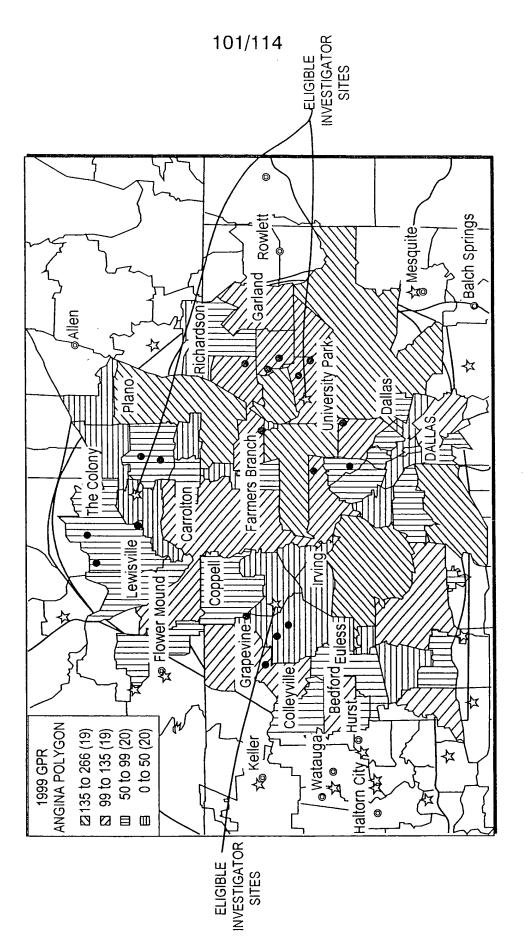


FIG. 22N

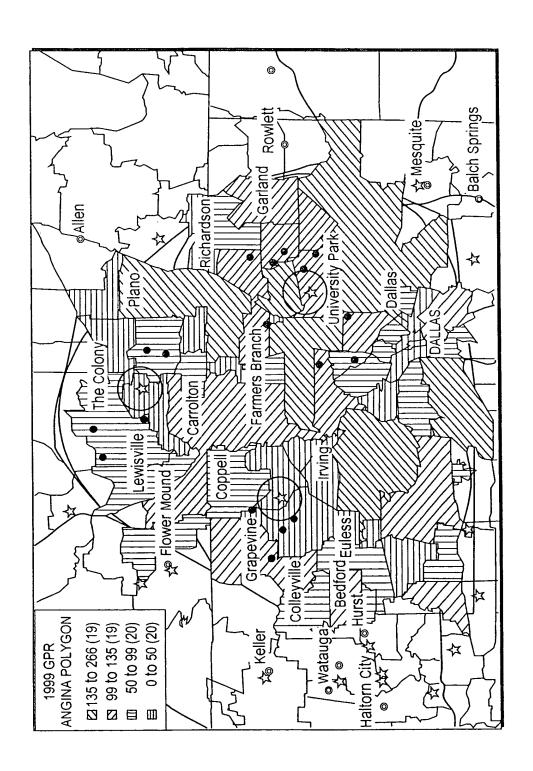


FIG. 22N

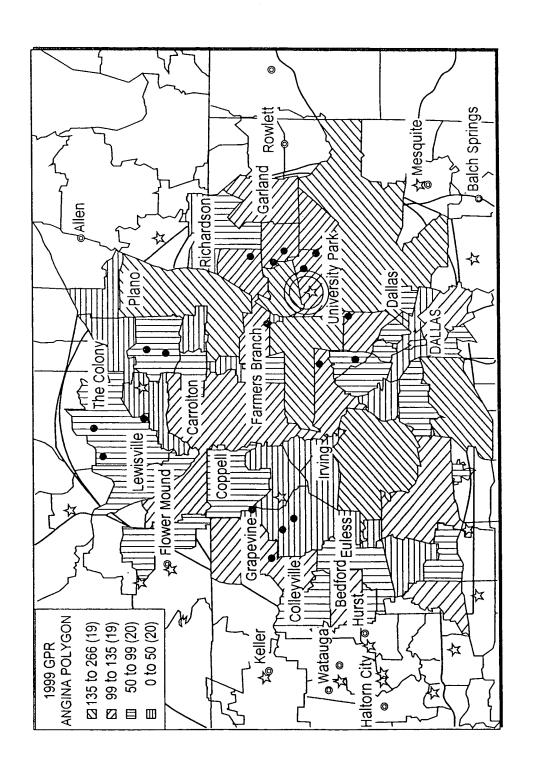
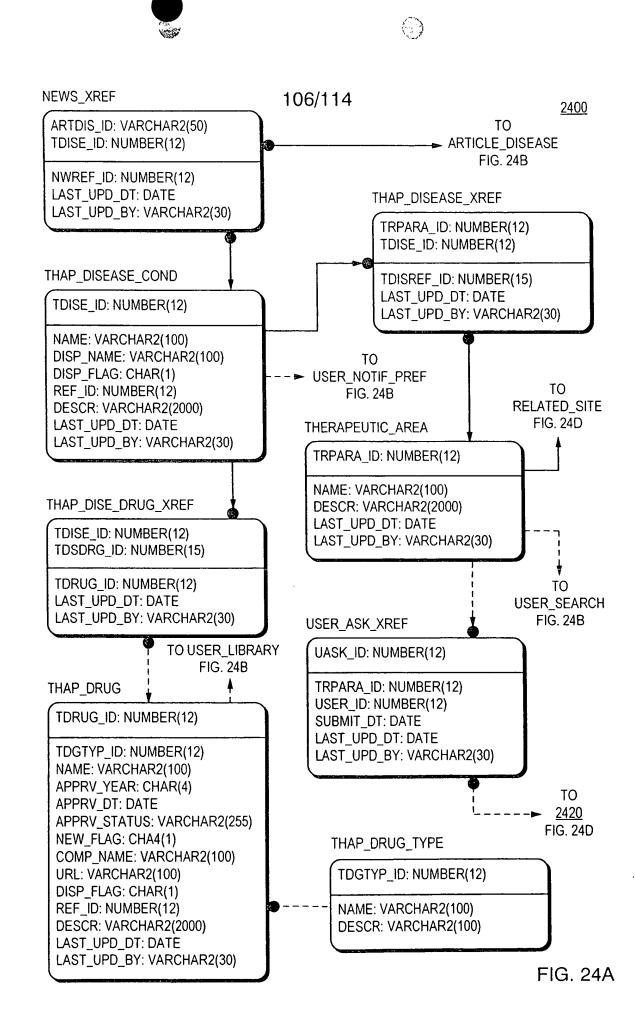


FIG. 22C

FIG. 22P

FIG. 23





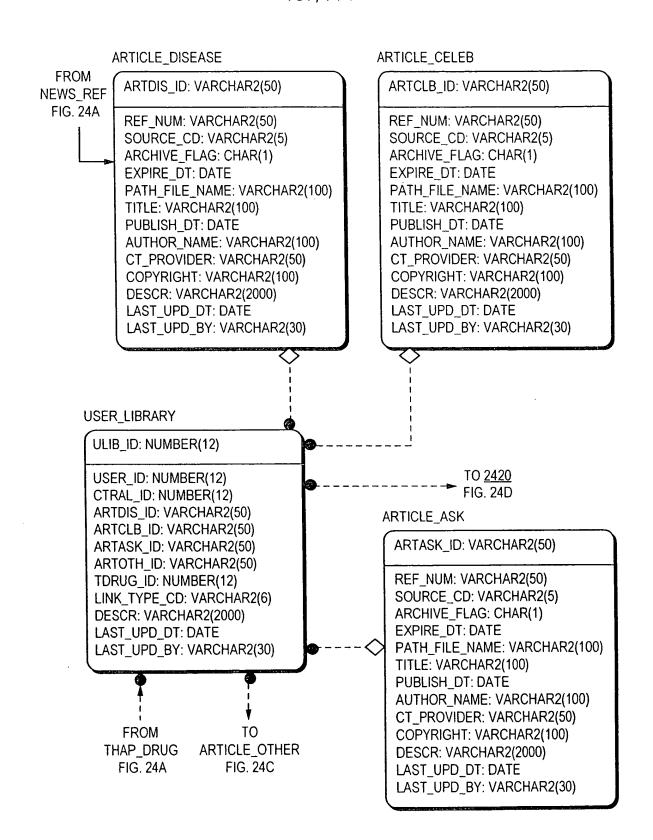


FIG. 24B



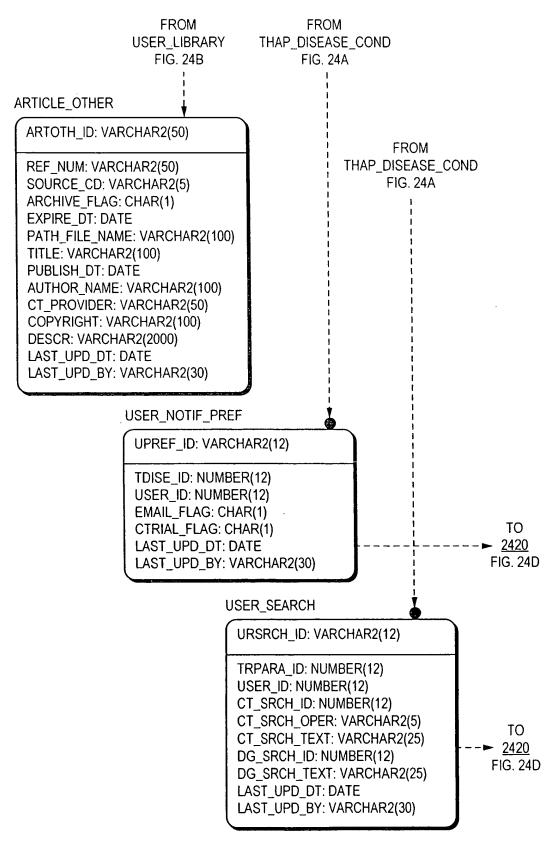


FIG. 24C

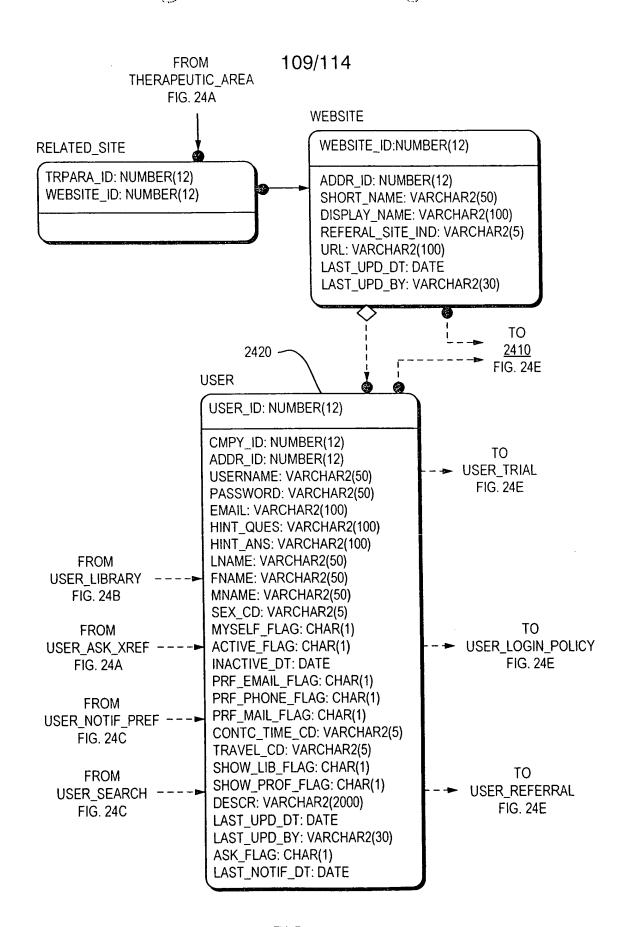


FIG. 24D



110/114 **ADDRESS** ADDR_ID: NUMBER(12) USER_TRIAL ADDR_LINE1: VARCHAR2(50) **FROM** USTRL_ID:NUMBER(12) WEBSITE-ADDR LINE2: VARCHAR2(50) ADDR_LINE3: VARCHAR2(50) FIG. 24D ADDR_ID: NUMBER(12) CITY: VARCHAR2(50) USER_ID: NUMBER(12) STATE CD: VARCHAR2(5) **FROM** EMAIL_FLAG: CHAR(1) ZIP CODE: VARCHAR2(10) <u>2420</u> PHONE FLAG: CHAR(1) PROVINCE: VARCHAR2(50) FIG. 24D MAIL_FLAG: CHAR(1) COUNTRY: VARCHAR2(15) LNAME: VARCHAR2(50) PHONE1_AREA: VARCHAR2(10) FNAME: VARCHAR2(50) PHONE1_NUM: VARCHAR2(10) EMAIL: VARCHAR2(100) PHONE1_EXT: VARCHAR2(10) 2410 PHONE2_AREA: VARCHAR2(10) DESCR: VARCHAR2(2000) LAST_UPD_DT: DATE PHONE2_NUM: VARCHAR2(10) LAST_UPD_BY: VARCHAR2(30) PHONE2 EXT: VARCHAR2(10) CTRAL_ID: NUMBER(12) LAST_UPD_DT: DATE LAST UPD BY: VARCHAR2(30) **FROM** USER_LOGIN_POLICY 2420 FIG. 24D URPCY_ID:NUMBER(12) ACURIAN CONTENT_TYPE **FROM** USER_ID: NUMBER(12) <u>2420</u> LOGIN_COUNT: NUMBER(5) FIG. 24D CONTYP_ID: NUMBER(12) ALLOW_LOGIN_DT: DATE RECOVERY_COUNT: NUMBER(5) NAME: VARCHAR2(100) RECOVERY_KEY: VARCHAR2(100) DESCR: VARCHAR2(100) RECOVERY_ALLOW_DT: DATE RECOVERY_DT: DATE ACURIAN_NOTIFICATION PASSWD_UPD_DT: DATE LAST UPD_DT: DATE NOTIF_ID:NUMBER(12) LAST UPD BY: VARCHAR2(30) CURRENT_LOGIN_DT: DATE NOTIF_TYPE: VARCHAR2(100) LAST_LOGIN_DT: DATE NOTIF_DESC.: VARCHAR2(100) LAST_NOTIF_DT: DATE USER REFERRAL URFAL_ID:NUMBER(12) ACURIAN_PUBLISH **FROM** USER ID: NUMBER(12) 2420 EMAIL: VARCHAR2(100) FIG. 24D PUBLISH ID: NUMBER(12) LAST_UPD_DT: DATE CONTYP_ID: NUMBER(12) LAST UPD BY: VARCHAR2(30) PUBLISH DATE: DATE TRPARA ID: NUMBER(12)

FIG. 24E

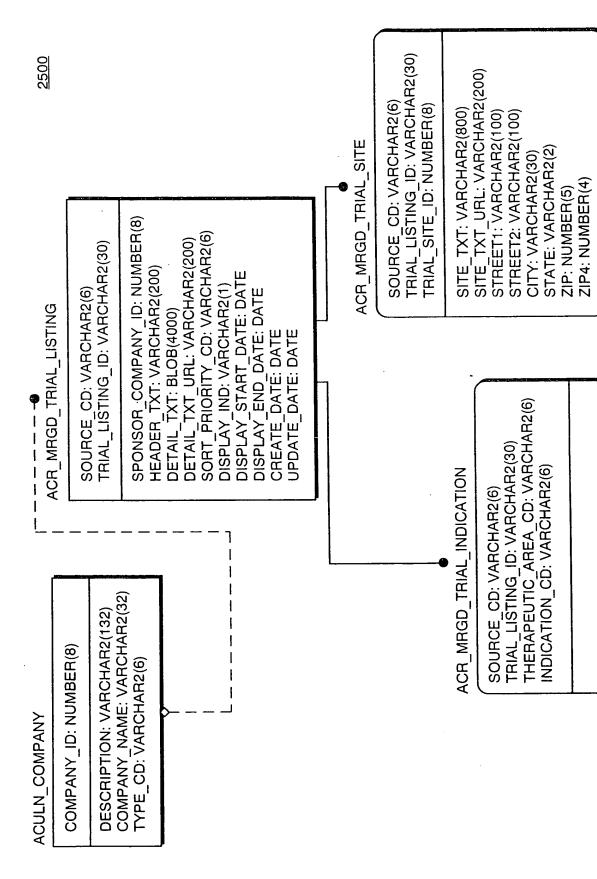


FIG. 25



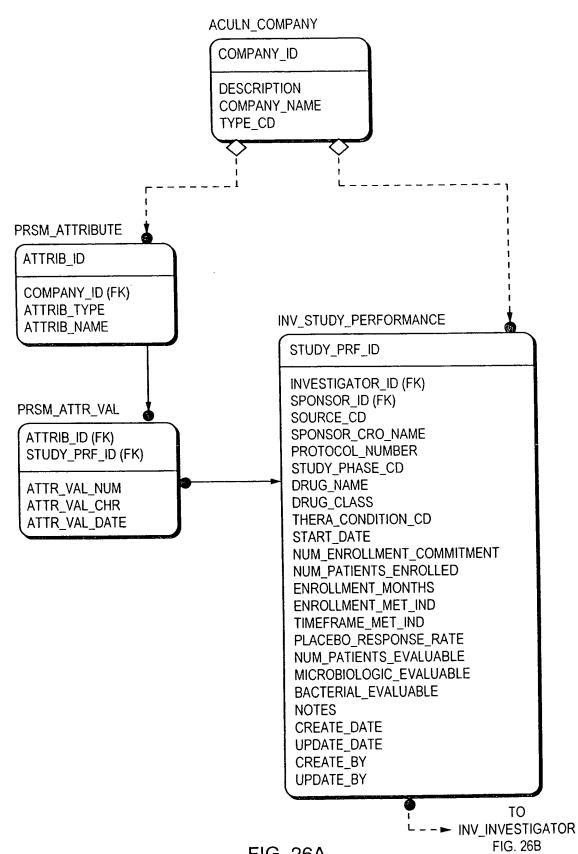


FIG. 26A

INV_INVESTIGATOR

INVESTIGATOR_ID

SOURCE_CD

HMS_ID

FIRST_NAME

MIDDLE1

MIDDLE2

LAST NAME

SUFFIX

COUNTRY

SOC_SEC_NBR

IND_UPIN

SEX

DOB

MED_SCHOOL_CD

GRADUATION_YEAR

RSDNCY_ORG

RSDNCY_CITY

FLLWSHP_ORG

FLLWSHP_CITY

DEGREE1

DEGREE2

PHONE_NBR

PHONE_EXTENSION

FAX_NBR

EMAIL

CREDENTIAL

DELETE_REASON_CD

DELETE_REQUEST_DATE

WRONG_NUMBER_IND

CV_RECEIVED_DATE

QUESTIONNAIRE_RETURNED_DATE

SMO_RELATIONSHIP_CD

PRACTIVE_TYPE_CD

PRIMARY_IN_OUT_CD

CRO_NUM_DAYS_NOTICE

PHASE1_EXPERIENCE_IND

PHASE2_EXPERIENCE_IND

PHASE3_EXPERIENCE_IND

PHASE4_EXPERIENCE_IND

PATIENT_DATABASE_IND

SOFTWARE_PACKAGE_NAME

CREATE_DATE

UPDATE_DATE

CREATE_BY

UPDATE_BY

FROM INV_STUDY_PERFORMANCE -FIG. 26A



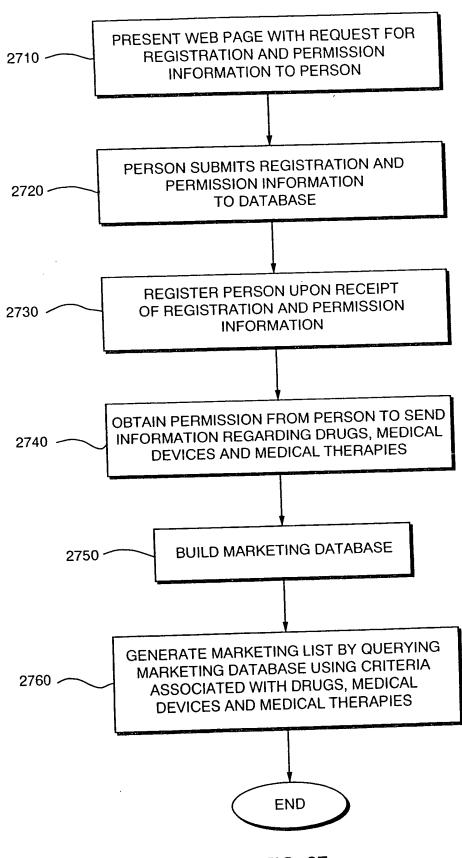


FIG. 27